



The American Journal for Nurse Practitioners

Clinical Challenges In...



PRIMARY CARE
Caring for Organ
Transplant Recipients

GERIATRICS
UTIs in the Elderly:
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Prevention

CLINICAL SUPPLEMENTS
Diaper Dermatitis: Smart
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Dear Colleagues,

Now is the time to let both candidates for President hear loudly and clearly that our healthcare system is in crisis. They need to understand that, as NPs, we are part of the solution for improved healthcare outcomes. Barriers to NP practice prevent many people from receiving the care that we are prepared to provide. As NPs, we have a fine opportunity to work with our physician colleagues to help craft a better healthcare system for the future. We must help our political leaders understand that the professions of medicine and nursing together are the hope for high quality care. This is 2008—we have an opportunity to let our voices be heard. Please take time to let the candidates know your concerns and creative ideas.

This issue of *The American Journal for Nurse Practitioners* offers a variety of topics that literally cover the life span. We start with "Diaper Dermatitis: Smart and Effective Management," by Carolyn Montoya, which provides new information about a common condition seen in the pediatric population. And "Women and Insomnia: An Update on Pharmacologic Management," by Anna K. Morin, is an excellent overview about a common problem in your female patient population. "Caring for Organ Transplant Recipients," by Raquel Marie Mahidashti helps us understand the major primary care problems faced by patients who have undergone organ transplantation. Finally, "Urinary Tract Infections in the Elderly: Symptomatology and Prevention," by Kelly Krause, Maria Mowassee, and Carolyn Auerhahn, offers insight into a UTI presentation in elderly patients that may be less than obvious.

We are pleased and proud to present a new column for *AJNP*—*From the Desk of Eileen T. O'Grady*. In this issue, Eileen discusses a special way to participate in modern political campaigns. Many of you will recognize this column from *NP World News*. In her Issues in Pharmacotherapy column, Mary Ann E. Zagaria discusses health literacy and how we can best meet our patients' needs in this area.

This is an exciting time for our nation, so let your voices be heard. We NPs have an opportunity to make a difference.



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Diaper Dermatitis: *Smart and Effective Management*

Carolyn Montoya, MSN, CPNP

Diaper rash—painful for the child and stressful for parents and caregivers—is a problem faced by every family. The modern lifestyle, with more parents working outside the home and more infants and children in daycare settings, highlights the need for a new approach to therapy for diaper rash. A new prescription product that combines three ingredients, including zinc oxide, white petrolatum, and an antifungal agent, miconazole nitrate, offers parents and caregivers a safe and effective option for treatment of diaper dermatitis complicated by Candida infection—the type of diaper rash that is the focus of this article. Parents and caregivers can benefit from counseling provided by nurse practitioners (NPs) on the causes, prevention, and management of diaper dermatitis.



For most parents, managing diaper rash is yet another rite of passage. But for the parent who is losing sleep, and for the infant who is miserable and in pain, diaper rash is more than just an annoyance. Diaper dermatitis, also referred to as irritant diaper dermatitis (IDD), is characterized by redness and irritation in the diaper area. Present in more than half of babies aged 4-15 months in any given 2-month period, diaper rash most commonly affects infants aged 9-12 months.¹ Diaper dermatitis is more common in older infants who have begun to eat solid foods, in infants who have diarrhea, and in infants who are taking antibiotics or being nursed by mothers who are taking antibiotics.¹

The economic impact of diaper rash is substantial. In 2006, more than 250,000 health care-related visits (inpatient, outpatient, and emergency department visits combined) were made for diaper rash.² Direct health-related costs are not the only factor affecting the total cost of care associated with diaper rash. In 2005, 61% of children <6 years old received care from someone other than their parent; most of these children were enrolled in center-based programs.³ If a parent who works outside the home needs to stay home to tend to an infant with severe diaper rash, then the parent will likely lose work

This article was made possible through support from Barrier Therapeutics, Inc.

time, which may reduce his or her vacation time and/or wages, thereby increasing the total economic burden of diaper rash. For children who are able to attend daycare, management of diaper rash is an additional burden on staff.

Causes and Clinical Presentation

The risk of diaper rash occurs whenever moisture, warmth, urine, feces, and friction coexist—in essence, anytime a diaper is left on for too long. Moisture leads to softening (maceration) of the outer protective layer of skin, which then becomes more susceptible to damage by friction from the surface of the diaper and further irritation by feces.⁴ Elevation in pH from ammonia in urine activates fecal lipase and proteases, which disrupt the normally acidic skin surface and allow for invasion by bacteria and yeast.

Diaper rash usually presents as a red, beefy rash in the diaper area (Table 1 and Figure 1). The rash may be bright red, raw, and weepy, with macules (flat, discolored lesions) or papules and inflamed, painful satellite lesions.⁵ Although bacterial infection is uncommon, diaper rash complicated by the presence of *Candida albicans* (diaper dermatitis complicated by candidiasis; DDCC) becomes more common when rash persists >72 hours.

Treatment and Prevention

As any new parent will tell you, babies do not come with an instruction manual. NPs should never assume that parents, especially first-time parents, understand the risk factors for and causes of diaper dermatitis, or the best approaches to treatment and prevention. Management of diaper rash can be influenced by culture and traditions. Education of par-

TABLE 1 SIGNS AND SYMPTOMS OF DIAPER DERMATITIS

Erythema	Smaller satellite rash
Pain	Papules and/or pustules
Location (diaper area)	Erosions
Beefy red rash within skin folds	Presence of <i>Candida</i>

ents should focus on treatment and prevention of recurrence.

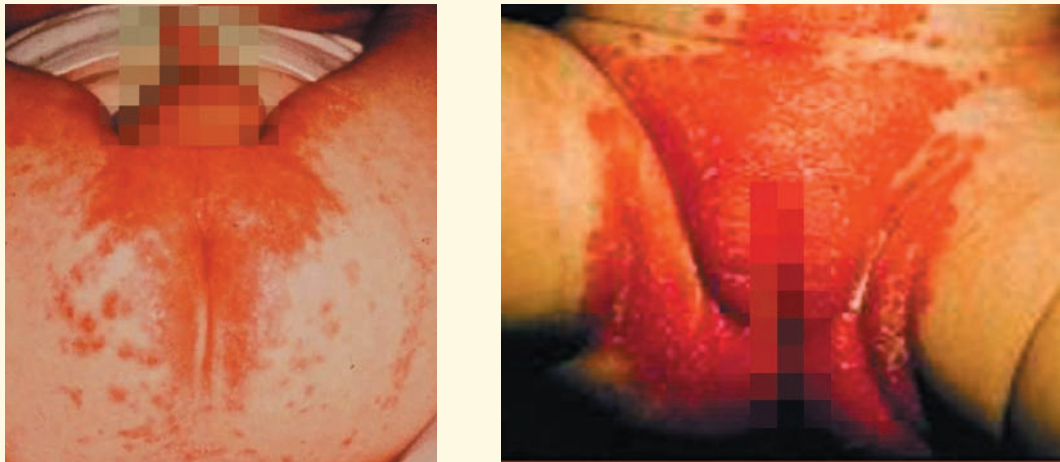
Prevention of first occurrence or recurrence of diaper dermatitis is as simple as keeping the diaper area as clean and dry as possible. Frequency of diaper dermatitis decreases in relation to the increased number of diaper changes.⁶ The American Academy of Pediatrics and the National Association of Neonatal Nurses recommend gentle cleansing with water or fragrance- and alcohol-free baby wipes, minimizing friction by pat-drying or air-drying, use of “barrier-type” protective ointments, and use of good-quality, absorbent, disposable diapers.³ Cloth diapers have been associated with increased incidence and severity of diaper dermatitis, likely due to increased skin exposure to moisture and feces.^{6,7} Although diaper-free time should be encouraged, this practice is not always possible, particularly in daycare settings.

Once a diaper rash has developed, goals of management are (1) to repair damaged skin; (2) to treat an underlying yeast infection, if present; and (3) to prevent recurrence. Repair of damaged skin is handled in much the same way as prevention of diaper rash, with emphasis on the use of proper barrier protection with a perfume- and allergen-free paste or ointment containing zinc oxide and/or petrolatum. Ointments, which are water-in-oil formulations with a

lipid content >50%, provide a superior moisture barrier and are more effective than creams or lotions.⁴ Antifungal therapy is used if the presence of *C albicans* is confirmed or suspected. At the present time, only one marketed product offers the combination of both zinc oxide and petrolatum and antifungal treatment with miconazole nitrate.⁸

Topical corticosteroid creams have little or no practical use in the treatment of diaper dermatitis, although some clinicians may occasionally recommend them. Topical corticosteroid creams can provide symptomatic relief in moderate or severe cases of IDD, but safer alternatives are available. Babies absorb disproportionately greater concentrations of topical medications than do adults.⁹ If used, topical steroids should be limited to hydrocortisone ointment ≤1% to the affected areas twice daily for a limited duration. Mid- to high-potency corticosteroids such as triamcinolone or betamethasone should *never* be used in the diaper area. In addition to the potential for systemic toxicity due to absorption, topical steroids may be associated with skin atrophy, striae, and erosions. Talcum powder should be avoided because this product offers no protection to the skin and can be abrasive and potentially harmful.⁴

FIGURE 1. | Clinical Presentation of Diaper Dermatitis Complicated by Candidiasis



Management of Diaper Dermatitis Complicated by Candidiasis

Infection with *Candida* becomes more likely when diaper rash persists >72 hours. *C. albicans* is a form of yeast present in the mouth and gastrointestinal tract of most infants. *Candida* usually exists in a unicellular form that, under the correct environmental conditions, changes into an invasive multicellular filamentous form. The environment in a soiled diaper—elevated pH, moisture, and warmth—is ideal for the spread of *Candida*. Candidiasis may be diagnosed by examining a skin scraping under the microscope following addition of a few drops of potassium hydroxide (KOH). Pseudohyphae and/or budding yeasts will be observed if *C. albicans* is present.

Miconazole Nitrate/Zinc Oxide Petrolatum/White Petrolatum Ointment—Only one combination product, Vusion® (0.25% miconazole nitrate, 15% zinc

oxide, and 81.35% white petrolatum) Ointment, is indicated for the treatment of DDCC in children as young as 4 weeks of age.⁸ A randomized clinical trial compared Vusion Ointment to vehicle control (zinc oxide petrolatum and white petrolatum) in 330 patients <4 years of age with clinical evidence of diaper dermatitis and a diaper dermatitis severity index score (DD SIS) ≥ 3 .¹⁰ The DD SIS is a composite index score of the sum of the severity of erythema, papules or pustules, and erosions

(Table 2). A total score of 3-4 is considered moderate and a score of 5-8 is considered severe. The study's outcome measure was overall cure or combined clinical response on the DD SIS and microbiologic response.

Demographics and mean baseline DD SIS of the patients in the two treatment groups were similar.¹⁰ Among the 330 children randomized, 236 were evaluable for response. On day 14 following initiation of treatment, children treated with the miconazole nitrate

TABLE 2 | DIAPER DERMATITIS SEVERITY INTENSITY SCORE (DD SIS)

Erythema	Papules/Pustules	Erosions
0 = none to trace	0 = none to trace	0 = none to trace
1 = mild	1 = few	1 = present
2 = moderate	2 = multiple	
3 = severe (beefy red)	3 = many	
	4 = abundant	

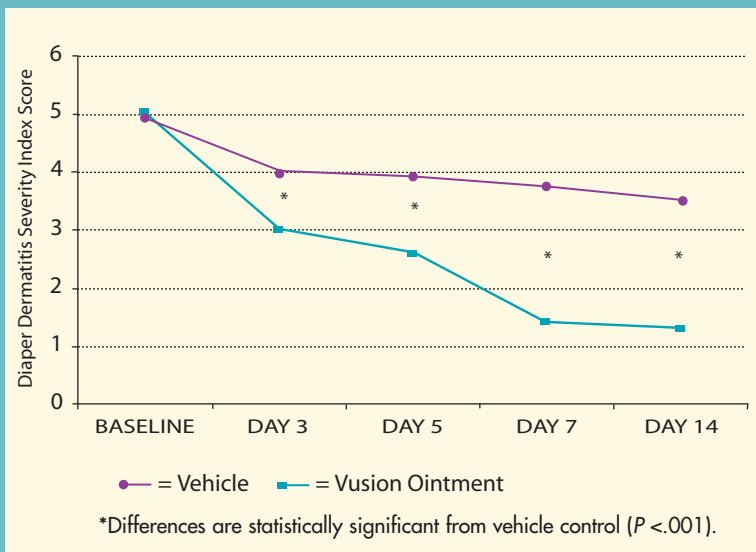
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FIGURE 2. | Diaper Dermatitis Severity Index Score by Study Day¹⁰



0.25%-containing ointment, compared with those treated with the vehicle control, had a significantly greater overall cure rate (23% vs 10%; $P = .005$) and clinical cure based on a DDSIS score of 0 (38% vs 11%; $P < .001$). Mean diaper dermatitis scores decreased from baseline for both treatment groups; however, mean scores for children treated with the miconazole nitrate ointment decreased more rapidly from baseline to day 14 and were significantly lower from day 3 through day 14 ($P < .001$) (Figure 2). By day 14, the mean DDSIS in the children treated with miconazole nitrate had decreased from 5.05 to 1.3 (74%), compared with a decrease from 4.98 to 3.52 (29%) in the children treated with the vehicle control. Although the zinc oxide/petrolatum vehicle control provided some degree of improvement over baseline, the miconazole nitrate 0.25%-containing ointment was associated with significantly greater improvement beginning at

day 3. Of note, only 4% of children randomized to miconazole nitrate 0.25% ointment withdrew from the study because of worsening or lack of improvement, versus 47% of children randomized to the vehicle control. Eradication of *C albicans* (microbiologic cure), as measured by KOH and culture, was documented in a greater percentage of children in the miconazole nitrate group than in the vehicle group both on day 7 and day 14 (Table 3).¹⁰

The miconazole nitrate 0.25%-containing ointment was well tolerated. Adverse events, reported in both the active and control arms of the study, were mild and none were considered to be related to study medication.¹¹ Adverse events reported in this trial included fever, rhinorrhea, upper respiratory tract infection, otitis externa, tonsillitis, croup, oral thrush, cold, otitis media, conjunctivitis, diarrhea, gastric disorder, gastroenteritis, vomiting, bronchitis, and rash.

The miconazole nitrate 0.25% ointment preparation has been evaluated in other clinical studies with a total enrollment of ~500 children, as well as in a pharmacokinetic study.¹¹ Evaluation of blood miconazole nitrate levels following application of miconazole nitrate 0.25% ointment or 2% cream demonstrated dramatically less systemic absorption of active drug with the ointment formulation (Figure 3). This pharmacokinetic finding translates into a potential for substantial improvement in the risk of adverse events in this very young patient population.

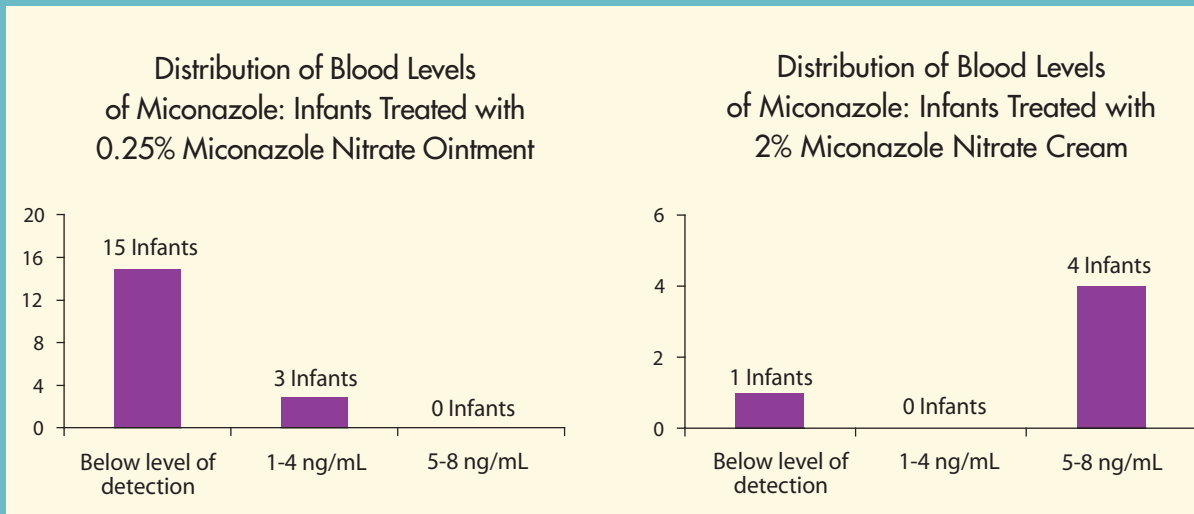
Other Products—Several prescription and over-the-counter (OTC) products have been used to treat DDCC. While topical nystatin cream is indicated for the treatment of cutaneous or mucocuta-

TABLE 3 | MICROBIOLOGIC ERADICATION RATES OF *CANDIDA ALBICANS*¹⁰

	Negative KOH		Negative Culture	
	Day 7	Day 14	Day 7	Day 14
Vusion Ointment	85%	90%	38%	50%
Vehicle	36%	72%	19%	23%

KOH = potassium hydroxide.

FIGURE 3. | Absorption Data Following Application of 0.25% Miconazole Nitrate Ointment and 2% Miconazole Nitrate Cream to Infants¹¹



neous infections caused by *C albicans*, it is not indicated for the treatment of diaper rash. Nystatin was first patented in 1957;¹² clinical trials of nystatin use in diaper rash were last published in the early 1980s.¹³ *In vitro* data indicate that, on average, the minimum inhibitory concentration of nystatin is 18.8 times that of miconazole nitrate.¹¹

Several products used for management of diaper dermatitis have potential safety problems associated with use in infants. This list includes topical OTC antifungal preparations that have not been evaluated in clinical trials of DDCC and carry a warning against use in children <2 years of age.¹⁴ Furthermore, use of topical vaginal antifungal creams can be problematic in that they are packaged with an applicator that can confuse parents who may think the product needs to be administered into the vagina or anus.

TABLE 4 PARENT COUNSELING—TREATING AND PREVENTING DIAPER DERMATITIS^{1,4,5}

- Change wet/soiled diapers as soon as possible.
- Wash affected areas with water or use non-perfumed or non-alcohol-containing baby wipes. Pat dry or air dry; do not rub.
- Use a barrier ointment containing zinc oxide and/or petrolatum with each diaper change. An approved antifungal or ointment product, such as Vusion Ointment, should be used in cases where *Candida* is confirmed.
- Infants with diaper dermatitis or those prone to it should receive daily lukewarm baths using an irritant- and fragrance-free cleanser.
- *Candida* infection can spread to other skin surfaces. Remind parents and caregivers of the need for good hand-washing after each diaper change. Although disposable gloves may be worn, they do not eliminate the need for good hand-washing.
- Contact your baby's healthcare practitioner if the diaper rash:
 - does not look as though it is healing or if it worsens 2-3 days after treatment, particularly if the baby is taking an antibiotic;
 - includes blisters or pus-filled sores; or
 - is associated with a fever.
- Avoid use of perfumed over-the-counter products, as well as those containing irritants, lotions, or creams; mid- to high-potency topical corticosteroids; or talcum powders.

REIMBURSEMENT OPTIONS

Vusion Ointment is covered by most insurance companies with co-pays of \$35-\$45. The manufacturer, Barrier Therapeutics (www.barriertherapeutics.com), offers a "1st Co-pay Assistance Program."



Patients with commercial prescription insurance can present the card to major chain pharmacies* to limit their co-pay to \$10.

Vusion Ointment is also on the formulary for most state-run Medicaid programs. Vusion (0.25% miconazole nitrate/15% zinc oxide/petrolatum/81.35% white petrolatum) Ointment is available by prescription in 50-gram tubes.

*Certain restrictions apply.

Conclusion

Choice of any product for use in infants must take into account efficacy, but even more important, safety and tolerability. Pediatric specialists have voiced concern regarding the use of pharmaceutical products in infants and children without the benefit of controlled clinical safety and efficacy data to back them up. Given the number of OTC products and remedies for diaper rash that are discussed and promoted on the Internet and in other media, NPs can understand why parents may be confused about how to manage a problem such as moderate to severe diaper dermatitis (useful tips for counseling parents appear in Table 4). In practice, consumers often choose products more on the basis of how they are marketed and less on the basis of safety and efficacy.¹⁵ Therefore, NPs need to counsel parents on how to recognize early signs of diaper dermatitis, particularly if complicated by *Candida* infection, and how to choose a product that will treat the episode of DDCC and prevent future episodes. Vusion Ointment, with a combination of miconazole nitrate and two forms of barrier

protection, represents a modern standard of care for DDCC. ■

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Only one combination product, Vusion Ointment, is indicated for the treatment of DDCC in children as young as 4 weeks of age.

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ELECTION 2008: Civic Engagement + Discount Store + Humility

Modern Campaigns and the Meaning of Service

A house in my neighborhood was available for rent recently and a most unusual tenant moved in. Suddenly, the house came alive, with many cars and young people coming and going 7 days a week. Shortly thereafter, campaign signs appeared in the yard and windows. I was delighted to learn that a candidate for the US House of Representatives and a health policy expert had established her 2008 Congressional campaign headquarters four doors down from my house. And so began my rather organic and unexpected experience working on a US Congressional campaign. Although I had hopes of working with her on policy and strategy, the reality of modern campaigning hit hard.

Instead of being called on to share my knowledge of health policy, I was asked to purchase, prepare, and display food for the primary night victory party (it was assumed she would win). This immediately created that familiar feeling of "role strain" from my early years as a new NP in which those around me did not know what I could do. In those early years, I refrained entirely from performing any tasks associated with the RN role in order to firmly establish my new role as an NP. The request to serve as caterer was surprising.

Opportunity is missed by most people because it is dressed in overalls and looks like work.

—Thomas Edison

My private logic and internal conversation went like this. "Do I say 'no' because preparing food threatens my ego? What does this say to the candidate and campaign staff about who NPs are and what we do and know? As a feminist, how does agreeing to do food service strengthen my role as a woman? How does this position me as a knowledge source? Do I do what needs to be done and do it well?" After thoughtful reflection, I decided that, because I was not willing to take the ultimate risk of running for Congress, I would serve as a Sherpa guide of sorts. Moreover, most of the campaign staff members were quite young and, if given the same responsibility, would probably have served cans of Cheez-whiz or other processed food.

On the 100-degree day of the

primary, my friend and I removed eight bags of trash and pizza boxes from the campaign headquarters to make room for the platters we assembled (always grateful for Costco!). My friend's expertise in catering was far beyond anything I could have imagined and we (she, really) put on a spread that was nothing short of presidential.

The staff, volunteers, and candidate herself had been working constantly for the previous 2 weeks to get out the vote on primary day. As they straggled in, hot and exhausted, from the polls that evening, they were astonished to see the colorful feast before them. The entire team was completely depleted from 'round-the-clock work, whereas I was able to move with great energy and serve the campaign in this small but important way.

Many things happened that night at the primary victory party, and I was so glad that I had agreed to give my time. Among the highlights: I got to know the candidate and campaign staff very well; I met a 2009 gubernatorial candidate and his staff and briefed them on nursing issues in the nation and the state (he was largely uninformed), suggesting that he get a nursing policy advisor for his campaign. I met the county supervisor and discussed a parking problem

OUR PREFERRED FUTURE IS BEFORE US

The APRN Consensus Report is being finalized after 4 years of intense discussion among all advanced practice nursing stakeholders. This report is a giant step toward success for all advanced practice registered nurses (APRNs) because it provides a compelling roadmap for state boards of nursing (BoNs) interested in aligning APRN licensing, accreditation, certification, and education (LACE). This report, if implemented, would significantly weaken our adversary's position that NP education is inconsistent and of poor quality. This report powerfully states that APNs should be regulated only by BoNs. When state BoNs meet this fall, they will ascertain how this new model can best serve the public and reduce inconsistencies and confusion about APRNs. If your state is interested in modernizing its Nurse Practice Act, this report will provide an extraordinarily sensible guiding framework for APRN regulation. This report goes a long way in strengthening the APRN movement as a whole. Conveners, leaders, and participants on this consensus document deserve a standing ovation. The report can be found at: https://www.ncsbn.org/7_23_08_Consensus_APRN_Final.pdf

in our neighborhood (pointing it out to him through the campaign headquarters window). He has since submitted an ordinance change and it is getting fixed.

As expected, another request came from the campaign. This time, I was asked to host a fundraiser in my own home. After thoughtful reflection, I agreed to do it and again met all kinds of wonderful people. At this venue, I met healthcare lobbyists and we created our plan to host a "Healthcare Reform Fundraiser"

for the candidate. This event is intended to organize support from nurses and other healthcare professionals for the candidate because of her healthcare expertise.

I offered to cater another fundraiser held on Capitol Hill for 30 people. Because catering drains scarce campaign resources and because of all these "opportunities" I've had thrust upon me in the past few months, I'm now nearly a pro at catering on the cheap. Because I was unable to attend this particular event, two campaign interns and I purchased and prepared the food, which the interns then delivered to the Hill. This effort took 90 minutes of my time and was a huge service to the campaign.

There are plans to hold a health reform debate among all the Congressional candidates in my region on healthcare reform. This debate will be sponsored by the Virginia Nurses Association, the Virginia Council of NPs, and other related health professional organizations. Participating in such a debate requires candidates to familiarize themselves with nursing issues and to develop a platform of creative solutions. In this capacity, I can use my analytic skills by crafting talking points for the candidate whom I support. This is the area in which the real fun starts; I find myself becoming giddy at the possibilities. My imagination comes alive, as in fiction writing. "If I were elected to Congress...."

What I have really enjoyed the most about this experience so far is being so close to the campaign and learning how it works. For example, I've watched how campaigns try to influence editorial boards of major newspapers to endorse them, and I've learned why candidates align or distance themselves from certain politicians or donors. And I've seen

how money flows between campaigns and national parties.

LESSONS LEARNED

Regardless of our own political stripe, we can learn lessons from thoughtfully selected service on campaigns. We can do profound deeds that may be unrelated to what we think is our area of expertise. There is intrinsic dignity in being open to serving on a political campaign.

Energy—I have learned that Congressional campaigns are short on glamour and high on youthfulness and positive energy. Planning a victory party before the election is a sign of an unshakable optimism regarding the outcome. Maintaining a positive outlook throughout a campaign is essential.

Opportunities—I have learned that, for the most part, opportunities to influence others and events come in small bits, not big chunks. We must be willing to avail ourselves of these opportunities, which may come from sources we never imagined. When we agree to perform a certain task, we find that serving selflessly at our highest competence level enriches not only those who ask for our services but also ourselves. All kinds of wonderful gifts can be extracted from a posture of unassuming service. Campaigns need content experts, but they also need volunteers who will do what needs to be done. Finally, I have learned that one can excel at catering campaign events on the cheap without anyone knowing.

FINAL COMMENTS

NPs need to become engaged citizens within our democratic society. This responsibility is derived from our core role as advanced practice nurses. With ongoing self-reflection, I have put aside my initial notions

Continued on page 26



Health Literacy: Striving for Effective Communication

Mary Ann E. Zagaria, PharmD, MS, RPh, CGP

Now, more than ever, patients are encouraged to take an active role in their own health care. But many patients thrust into a participatory healthcare system lack the necessary communication skills to navigate confusing and complex instructions and information to make appropriate decisions and adhere to their agreed-upon plan of care. Nurse practitioners (NPs) may be surprised to learn that about one third of the adult population in the United States (~90 million persons) have limited health literacy.^{1,2}

Persons with limited health literacy, compared with those with adequate health literacy, tend to have less knowledge about health and worse health status, are more likely to make medication errors, and incur higher healthcare costs.² Furthermore, according to the American Medical Association, poor health literacy is a stronger predictor of a person's health than are age, income, employment status, education level, and race.³ NPs should become familiar with the issues surrounding health literacy and with specific examples of how low health literacy compromises health outcomes. This column addresses these issues and directs NPs toward clinical assessments

and communication techniques that will enhance their interactions with patients.

Whereas literacy is the ability to read, *health literacy* is much broader, encompassing the ability to read, understand, and act on health-related information.^{1,3} More specifically, according to the US Department of Health and Human

Services (HHS) report *Healthy People 2010*, health literacy is defined as the degree to which people can obtain, process, and understand basic health information and services needed to make appropriate health decisions (Table 1).^{2,4} In addition, HHS has identified health literacy as an important component of health

TABLE 1 COMPONENTS OF HEALTH LITERACY^{2,4}

Health literacy requires the following:

- Reading
- Listening
- Analytical skills
- Decision-making skills
- The ability to apply the above skills to health situations
- Numeracy (using numbers and thinking in quantitative terms to complete tasks; for example, a patient with diabetes who can perform computations to calculate the number of calories in a serving of ice cream or to measure medications)

Health literacy includes the ability to understand instructions on:

- Prescription medication containers
- Over-the-counter medication labels
- Appointment slips
- Medical education brochures
- Practitioner's directions
- Consent forms

Health literacy includes the ability to navigate complex healthcare systems.

communication, medical product safety, and oral health.³

One national assessment of adult literacy indicated that 14% of US adults have *below basic* health literacy, defined as being non-literate in English or being able to perform only the simplest and most concrete health literacy tasks (eg, circling the date of a health appointment on a calendar).^{2,5} Another 22% have *basic* health literacy, defined as the ability to perform simple health literacy activities (eg, locating one piece of information in a short document).^{2,5} Approximately 53% have *intermediate* health literacy (eg, being able to determine a healthy weight for themselves using a body mass index chart), but only 12% percent of US adults have *proficient* health literacy, wherein they possess the necessary skills to adequately manage their health and prevent diseases.^{2,5}

A correlation between low health literacy and poor health is substantiated through evidence-based literature reviews.³ Adults with low health literacy, compared with those with higher health literacy, (1) adhere less often to prescribed treatment and self-care regimens, (2) make more medication errors, (3) do not seek preventive care, (4) are at a higher risk for hospitalization, (5) require longer hospitalizations and have a higher use of expensive emergency services, and (6) lack necessary skills to navigate the healthcare system.^{1,3}

Special Populations

Studies have shown the adverse impact of low literacy in specific patient populations (Table 2).^{3,5-7} For example, in patients with type 2 diabetes, low health literacy is independently associated with worse glycemic control and higher rates of retinopathy.^{3,8} One study

showed that, despite having attended formal education classes, approximately half of the patients with diabetes or hypertension had inadequate health literacy and that these individuals, compared with their more health-literate counterparts, had significantly less knowledge about their disease, lifestyle modifications, and self-management skills.^{3,9} Low health literacy has also been strongly correlated with poorer knowledge about asthma or proper use of metered-dose inhalers.^{3,10} With reference to cancer, low health literacy adversely affects incidence, mortality, and quality of life.^{3,11}

Medication Adherence and Medication Errors

Prescription labels, patient education handouts, and instructions for prescription and nonprescription medications are often complex and written at a level exceeding the literacy skills of the typical US adult.² In addition, patients with low health literacy have difficulty understanding auxiliary warning labels on prescription bottles.² Therefore, many patients cannot understand medication instructions or self-administer medications correctly.² These mistakes are most likely to occur among mem-

bers of the age group with the highest reported rate of limited health literacy—the elderly.^{2,12}

Low Literacy and the Elderly

Two thirds of US adults aged ≥ 60 years have inadequate or marginal literacy skills, according to some estimates.^{2,13} Among community-dwelling older adults, inadequate health literacy is independently associated with poorer physical and mental health.¹⁴ Patients who misunderstand their diagnosis and treatment plans tend to adhere poorly to therapy (eg, medication and diet regimens, lifestyle changes).¹⁵ This concept is key for NPs in terms of developing a plan of care or a medication counseling approach. Patients with low health literacy may misinterpret or have difficulty understanding prescription drug warning labels and written patient education materials.¹⁶ This misunderstanding can adversely affect the health and well-being of older adults, many of whom struggle with the management of co-morbidities that require complex medication regimens.¹⁶ When appropriate, NPs should consider including family members and caregivers in the patient education process, which may improve adherence.^{15,16} Among

TABLE 2 CATEGORIES OF INDIVIDUALS VULNERABLE TO LIMITED HEALTH LITERACY^{3,5-7}

- Adults aged ≥ 65 years
- Minority populations: Hispanics, African Americans, and American Indians/Alaskan Natives
- Low-income individuals (approximately half of Medicare/Medicaid recipients read below a fifth-grade level)
- Persons in poor health (eg, those with chronic mental and/or physical conditions)
- Immigrant populations (eg, those whose English proficiency is limited)

many older adults in Medicare managed-care programs, low health literacy can interfere with the use of preventive services, including influenza or pneumococcal vaccination, mammography, and Papanicolaou testing.¹⁶⁻¹⁸

Informed Consent—NPs should consider low health literacy with regard to informed consent. When patients sign an informed consent form to undergo surgery or participate in a research study, do they fully understand the implications? One study, which evaluated informed consent for research, showed that comprehension varied inversely with age and directly with education level.^{19,20} This finding may also be relevant in the realm of advance care directives and do-not-resuscitate orders for seniors.¹⁶

Hearing Impairment—As the population ages, NPs will encounter more and more patients with hearing limitations.²¹ In a Harvard Medical School study, participants who were deaf or hearing impaired suggested that clinicians ask patients about their preferred communication approach (eg, lip-reading, sign language, writing notes).²¹ The study also showed that asking patients to repeat critical health information (eg, medication instructions) is a way to identify potentially dangerous miscommunication.^{6,21}

Improving Communication

In two separate reports, the Institute of Medicine has indicated that healthcare practitioners must redesign the system of healthcare delivery to meet the needs of low-literate individuals.⁵ According to the National Patient Safety Foundation, communication breakdowns are the leading source of medical errors.³ This finding serves as the basis for the foundation's

RESOURCES

Ask-Me-3

<http://www.npsf.org/askme3/>
Health literacy program sponsored by the Partnership for Clear Health Communication, a national coalition of more than 100 organizations working together to promote awareness of and solutions to the problem of low health literacy and its effect on health outcomes

Health Literacy Studies

<http://www.hsph.harvard.edu/healthliteracy/index.html>
Harvard School of Public Health
Department of Society, Human Development and Health
677 Huntington Avenue, 7th Floor, Boston, MA 02115

Health Literacy Consulting

<http://www.healthliteracy.com/>
31 Highland Street, Suite 201, Natick, MA 01760
(508) 653-1199

Healthy People 2010: Understanding and Improving Health

<http://www.healthypeople.gov/Document/pdf/uih/2010uih.pdf>
US Department of Health and Human Services

National Institute for Literacy

<http://www.nifl.gov/>
1775 I Street N.W., Suite 730, Washington DC 20006-2401
(202) 233-2025

Health Literacy and the Older Adult (self-learning module)

<http://healthlit.fcm.arizona.edu/>
University of Arizona Reynolds Program in Applied Geriatrics

promotion of the health literacy program entitled *Ask Me 3* (see Box), which promotes three simple but essential questions that patients should ask practitioners in every healthcare interaction: (1) What is my main problem? (2) What do I need to do? and (3) Why is it important for me to do this?³

Assessing for Limited Literacy—Practitioners commonly underestimate the prevalence of low health literacy in their patient population while overestimating their patients' ability to understand the information they provide.² Healthcare professionals need to learn the prevalence of limited health litera-

cy in their practice through the use of instruments designed to assess health literacy skills of a sample of patients.² These assessment tools are easy to use, available in English and Spanish, and take only 2-3 minutes in some cases; in addition, their use is well accepted by patients.² The three most widely used tools are the Newest Vital Sign (NVS), the Rapid Estimate of Adult Literacy in Medicine (REALM), and the Test of Functional Health Literacy in Adults (TOFHLA). These and other tools are described in detail in reference 2, which is available online.

Communication Methods—Effective communication tech-

niques can be used to improve interactions with all patients, but these techniques are especially important in a practice with a high proportion of patients with limited health literacy.² NPs are encouraged to use the following communication methods: talk more slowly, use nonmedical language, limit the amount of information imparted, use teach-back (ie, ask patients to repeat what they were told that they need to do and verify that they understand), and encourage questions (see comments pertaining to these methods, which are listed in Table 2 of reference 2).^{2,22} The potential for improved health outcomes, such as improved diabetic control when practitioners use the teach-back technique to verify that patients understand what they need to do, is supported by emerging evidence.²

FROM THE DESK OF EILEEN T. O'GRADY

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and expectations about working on a Congressional campaign. With careful listening and openness, I am able to serve in a way that affects the campaign in unexpected ways. It is not too late to participate in the political process. I have experienced firsthand the concepts of service and citizenship in a deeper way by using my tools of reflection and relationship-building. There are countless ways to demonstrate and express the fundamental importance of civic engagement and effective citizenship. As socially responsible professionals, we must do more than just assert this ambition.

Dr O'Grady is a nurse practitioner who lives near Washington, DC. She can be reached at e.ogrady@verizon.net

Conclusion

Evidence-based literature reviews indicate the correlation between low health literacy and poor health. Poor health outcomes such as higher rates of hospitalization and less frequent use of preventive services are associated with higher health-care costs; both problems are linked to low literacy. About one third of US adults have limited health literacy, causing them to have difficulty in understanding information provided by health-care practitioners and in making appropriate healthcare decisions. Because people are expected to assume a more active role in healthcare decision making as patients or as caregivers, NPs can make a difference in their lives by being aware of and understanding the implications of low literacy and using assessment tools and communication methods to enhance health-related interactions between themselves and their patients.

Dr Zagaria is a Senior Care Consultant Pharmacist and President of MZ Associates, Inc., in Norwich, NY. She is also a certified adult basic literacy tutor.

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WOMEN AND INSOMNIA:

An Update on Pharmacologic Management

Anna K. Morin, PharmD, RPh

INSOMNIA is a common and costly sleep disorder with a lifetime prevalence of 30%-35% in the general population.¹ Numerous disease states and medications can cause sleep disturbances (Table 1).^{2,3} Chronic insomnia, affecting at least 10% of patients experiencing sleep disturbances, has been associated with a greater risk for the development of psychiatric disorders, such as depression and anxiety, and physical disorders, such as

cardiovascular disease, chronic obstructive pulmonary disease, peptic ulcer disease, chronic pain, and obesity.^{2,4} Other consequences of insomnia include daytime fatigue, impaired concentration, poor job performance, and an increased risk of accidents. Women, the elderly, and persons with physical or psychiatric comorbidities are at particular risk for insomnia.^{2,4} Gender differences in insomnia may be related to risk

factors for insomnia, such as depression and anxiety, which are more prevalent in women than in men.⁵ Other gender differences that may affect sleep include hormonal and physical changes that women encounter throughout the life cycle. Ultimately, women are more likely to present with complaints of sleep disturbances and, therefore, are more likely to be prescribed pharmacotherapy for the treatment of insomnia.⁵

Learning Objectives

After participating in this educational activity, participants should be able to:

- Delineate the weaknesses, the misconceptions, and the advantages of various pharmacotherapies available for treatment of insomnia.
- Develop strategies to effectively manage patient expectations and evaluate long-term treatment in appropriate patients with chronic insomnia.

Target Audience

- Nurse practitioners
- Nurses
- Nurse-midwives

To complete the post-test for this activity, which is available online, please visit www.npwh.org and click on CE Activities under the Professional Education drop-down menu.

Continuing Education (CE) Activity Information

The release date for this activity is July 23, 2008, and the expiration date is July 23, 2009. Estimated time to complete this activity is 1 hour.

Disclosure of Conflicts of Interest

As a provider and approver of continuing education for nurse practitioners, NPWH must ensure balance, independence, objectivity, and scientific rigor in all of its directly or jointly sponsored educational activities. Therefore, anyone who is in a position to influence or control the content of a CE activity must disclose any financial interest or other relationship with a commercial interest producing healthcare goods or services that have a direct bearing on the subject matter of the CE activity. Significant financial interest or other relationship may include grants or research support or serving as an employee, consultant, member of a speaker's bureau (or the like), or major stockholder—any interest or relationship that has occurred for any dollar amount over the past 12 months. The intent of disclosure is not to prevent a speaker with a significant financial or other relationship from making a presen-

Normal Sleep Cycle

Based on circadian rhythms and the activity of various neurotransmitters, sleep is divided into two primary phases: rapid eye movement (REM) sleep and non-REM sleep.⁶ Essential for health maintenance, *non-REM* sleep occurs throughout the night in four cyclic stages (stages 1-4). Stage 1 is the transition from drowsiness to sleep and comprises 3%-8% of total sleep time in an average adult. This stage is characterized by slow rolling eye movements and theta brain waves and minimal alpha waves on an electroencephalogram (EEG). Sleep officially begins at stage 2, which accounts for 45%-55% of overall sleep in an average adult and is characterized by light or intermittent sleep with rapid alpha wave rhythm on EEG. Stages 3 and 4 involve deep sleep, with slow-wave, high-voltage EEG delta wave rhythm. An average adult spends 3%-8% and 10%-15% of total sleep time in stages 3 and 4, respectively.

REM sleep (often referred to as stage 5 sleep) occurs 60-90 minutes into sleep and accounts for 20%-25% of total sleep time.⁶ REM sleep is essential for learning and mood regulation and is characterized by rapid eye movement, muscle atonia, heightened dream activity, and EEG activity similar to that of stage 1 sleep. The first REM stage lasts 5-7 minutes, with each REM cycle lasting longer (15-40 minutes) as the time spent in stages 3 and 4 decreases during the night. *Sleep architecture* is the term used to define the progression through the five organized and repeating stages of sleep.⁶

Insomnia

Sleep disturbances associated with insomnia include difficulty falling asleep (delayed *sleep latency*), difficulty staying asleep (impaired *sleep maintenance*), and/or nonrestorative sleep leading to substantial impairment in social and occupational functioning.^{7,8} Based on the duration of symptoms, insomnia is

often further categorized as transient (1-3 nights), short-term (>3 nights and <1 month), or chronic (>1 month).^{7,8} Sleep disturbances can exist independent of other disorders or conditions or be associated with other physical or psychiatric conditions (co-morbid insomnia).^{4,7} The clinical significance of insomnia is based on the frequency, intensity, and duration of symptoms, as well as the associated adverse effects of the sleep disturbance on daily activities and overall quality of life.⁴

Treatment of Insomnia

Numerous nonpharmacologic and pharmacologic therapies ranging from herbal remedies to over-the-counter (OTC) products to prescription products are available for the treatment of insomnia. Treatment of any underlying or co-morbid physical or psychological disorder should be addressed before considering a treatment strategy for the sleep disturbance. Before the implementation of any

tation but, rather, to resolve any conflicts prior to the CE activity so the learner may participate in a balanced, objective, evidence-based CE activity.

Anna K. Morin, PharmD, RPh, discloses that she has no financial relationships relevant to the content of this CE activity.

CPE Communications, as the educational partner to the NPWH, wishes to disclose an ongoing relationship with Takeda Pharmaceuticals North America, Inc. CPE Communications has received educational grant funds from Takeda Pharmaceuticals North America for the creation of CE materials. Jeanne Prater and Jennifer Wietzke, PhD, CPE Communications, have disclosed that they have no relevant financial relationships with any commercial interests.

Accreditation Statement

This activity has been evaluated and approved by the Continuing Education Approval Program of the National Association of Nurse Practitioners in Women's Health for 1 contact hour of continuing education credit, including 1 hour of pharmacology content.

This activity has been planned in accordance with the

standards and policies of the National Association of Nurse Practitioners in Women's Health. The activity is accredited for nurse practitioners, nurses, and nurse-midwives.

Faculty Biography

Anna K. Morin, PharmD, RPh, is Associate Professor in the Department of Pharmacy Practice, Massachusetts College of Pharmacy and Health Services, Worcester, where she won the "Teacher of the Year" award in 2007. Dr Morin is also a member of the American College of Clinical Pharmacists and the American Association of Colleges of Pharmacy. She has published widely on both pharmacologic and cognitive behavioral management of insomnia in journals such as *Pharmacotherapy*, *American Journal of Lifestyle Medicine*, and *US Pharmacist*.

This educational activity is jointly sponsored by the National Association of Nurse Practitioners in Women's Health (NPWH) and CPE Communications.

This program is supported by an independent educational grant from Takeda Pharmaceuticals North America, Inc.

TABLE 1

DRUGS AND DISEASE STATES KNOWN TO CAUSE SLEEP DISTURBANCES^{2,3}

Drugs

- Adrenocorticotropin and cortisone
- Antibiotics (eg, quinolones)
- Antidepressants (eg, selective serotonin reuptake inhibitors, bupropion)
- Antihypertensives (eg, alpha agonists, beta blockers, central-acting adrenergic blockers)
- Antineoplastic agents
- Appetite suppressants
- Beta agonists
- Caffeine
- Decongestants (eg, ephedrine, pseudoephedrine)
- Diuretics
- Dopamine agonists
- Ethanol
- Lipid- and cholesterol-lowering agents
- Oral contraceptives
- Psychostimulants (eg, amphetamines)
- Sedatives/hypnotics
- Theophylline
- Thyroid preparations

Disease States

Physical

- Cardiovascular (angina, arrhythmias, heart failure)
- Respiratory (asthma, sleep apnea)
- Chronic pain
- Endocrine disorders (diabetes, hyperthyroidism)
- Gastrointestinal (gastroesophageal reflux disease, ulcers)
- Neurologic (delirium, epilepsy, Parkinson's disease)
- Pregnancy

Psychiatric

- Mood disorders (depression, mania)
- Anxiety disorders (generalized anxiety disorder, obsessive-compulsive disorder, post-traumatic stress disorder, panic disorder)
- Substance abuse

treatment strategy, a thorough assessment of an individual's physical history, psychiatric history, medication history (prescription, OTC, and recreational drugs), and family sleep disorder history should be performed. Treatment is individualized to address the frequency, intensity, duration, and adverse outcomes associated with the sleep disturbance.

Nonpharmacologic Therapies—

Nonpharmacologic treatment approaches to insomnia are preferred in patients who are reluctant to use pharmacotherapy because of the adverse effects associated with these medications. Women who are pregnant or breast-feeding and experiencing insomnia must pay particular attention to the safety of medications.⁵ Techniques that encompass behavioral and cogni-

tive nonpharmacologic approaches to the treatment of sleep disturbances are outlined in Table 2.⁹ Required clinician training in various techniques, the limited number of controlled studies, and delayed improvements in sleep parameters can limit the usefulness of nonpharmacologic therapies for insomnia. At the very least, every patient who presents with sleep complaints should be educated regarding proper sleep hygiene (Table 3).⁹ When used alone, sleep hygiene education has shown limited efficacy but can be useful when used as augmentation to pharmacotherapy.

Pharmacologic Therapies—

Pharmacotherapy is the most frequently used intervention for insomnia and is indicated when sleep disturbances produce sub-

stantial impairment and immediate relief is required. Commonly used classes of sedative-hypnotic agents include benzodiazepines (BZs), nonbenzodiazepines, melatonin receptor agonists, trazodone, sedating antihistamines, and herbal preparations.^{4,8,10} These central nervous system (CNS) depressants produce drowsiness and calming effects (sedation) that lead to the onset and maintenance of sleep (hypnosis).^{4,10} An ideal sedative-hypnotic agent should mimic a physiologic sleep pattern, have an appropriate duration of action (depending on the sleep complaint), have good tolerability, and enhance next-day functioning.² Many of the marketed sleep agents, although safe and effective when taken as directed, fall short of these ideals.

Benzodiazepines

Benzodiazepine-receptor agonists are often used as first-line treatment of insomnia. BZs approved by the US Food and Drug Administration (FDA) for use as sedative-hypnotics include estazolam, flurazepam, quazepam, temazepam, and triazolam.^{4,8,10,11} Because of their abuse potential, these agents are all categorized as schedule C-IV by the Drug Enforcement Agency (DEA).¹¹

BZs enhance the activity of gamma-amino butyric acid (GABA), the primary inhibitory neurotransmitter in the CNS, by binding at the GABA_A receptor site.^{10,11} The GABA_A receptor contains two subtypes: the BZ₁ (or omega₁) receptor and the BZ₂ (or omega₂) receptor. Stimulation of the BZ₁ receptor plays a role in the onset of sleep and the maintenance of sleep architecture. Stimulation of the BZ₂ receptor plays a role in the maintenance of memory, learning, and sensory and motor function.^{10,11}

TABLE 2 NONPHARMACOLOGIC STRATEGIES FOR INSOMNIA⁹

Activity	Description
Stimulus-control therapy	Helps associate sleep stimuli with falling asleep; goal is re-establishment of a regular sleep-wake cycle
Sleep restriction	Time spent in bed limited to actual sleep time; goal is mild, temporary sleep deprivation that leads to faster sleep onset and improved sleep maintenance and quality
Relaxation training	Methods include progressive muscle relaxation, biofeedback, rhythmic breathing, imagery training, and meditation; goal is to reduce autonomic (ie, stress and muscle tension) and cognitive (ie, intrusive thoughts) arousal stimuli that interfere with sleep
Paradoxical intention	Patients stay awake as long as possible to decrease anxiety about falling asleep and the consequences of sleeplessness; goal is to change unrealistic sleep expectations
Sleep hygiene education	Recommendations regarding sleep behaviors and environmental factors that may affect quality and quantity of sleep
Cognitive therapy	Patient-specific unrealistic expectations about sleep requirements addressed; goal is to identify and change misconceptions about causes of sleep disturbances

These GABA_A receptor subtypes are composed of five protein subunits (two alpha, two beta, and one gamma) arranged in a pattern around a chloride ion channel. Nonselective activation by a BZ opens these pentameric receptor channels, leading to an increased influx of chloride and enhanced GABA activity.^{10,11} In general, BZ activity at the GABA_A receptor results in sedation, anterograde amnesia, anticonvulsant activity, anxiolytic effects, muscle relaxation, ataxia, and ethanol potentiation. BZ modification of the sleep cycle can lead to a decrease in sleep latency, a decrease in the number of awakenings during the night, and an increase in the total time spent asleep.^{3,10,11}

Use of an appropriate BZ is based on the presenting sleep complaint(s) and the onset and duration of action of the individual agent. Pharmacokinetic param-

eters, recommended doses, and indications for individual BZ agents are summarized in Table 4.^{4,8,11-18} An agent with rapid onset and short duration (eg, triazolam) is most appropriate for patients whose primary sleep disturbance is difficulty falling asleep. An agent with a longer duration of action would be appropriate for patients

with numerous awakenings or early awakening.

Studies have confirmed the safety and efficacy of BZs as a class when used for short periods (<2 weeks) at recommended doses.^{2,19} Common adverse effects of BZs include dizziness, headache, and next-day residual drowsiness.^{2,11,19} Other unwanted effects include alteration of sleep architecture (increased time spent in stage 2 sleep, with shortened stage 4 sleep and REM sleep), residual daytime sedation, cognitive and psychomotor impairment, anterograde amnesia, and withdrawal symptoms and rebound insomnia upon abrupt discontinuation.^{11,19} Residual daytime sedation ("hangover effect") has been associated with BZs with a long duration of action (eg, flurazepam, quazepam), and patients report a decrease in mental alertness, headache, and a feeling of slowness upon awakening.¹⁹ Amnesia and memory impairment are dose dependent and have been most often reported with triazolam and lorazepam (a BZ often used for insomnia despite not being FDA approved for this indication).^{11,19}

Tolerance to the sedative-hypnotic effects of BZs and physical

TABLE 3 SLEEP HYGIENE GUIDELINES⁹

- Attempt to maintain a regular sleep-wake cycle, even after a poor night's sleep
- Avoid excessive wakeful time in bed (ie, >15-20 minutes)
- Use the bedroom for sleep and intimacy only
- Create a comfortable, quiet, dark, and temperature-controlled bedroom environment
- Develop a relaxing routine that is maintained within 1 hour of bedtime
- Exercise regularly, but not within 3-4 hours of bedtime
- Avoid heavy meals before bedtime
- Avoid napping during the day
- Avoid disturbances at bedtime and during sleep (eg, disruptive noises, pets)
- Avoid "clock watching" by removing a bedside clock

dependence most often occurs with long-term use of BZs. Withdrawal symptoms may include dysphoria, abdominal cramping, vomiting, diaphoresis, tremor, and, rarely, seizures.^{11,19} Rebound insomnia manifests as a rapid return of original sleep difficulties, but of worse severity than before treatment. BZs with a short or intermediate duration of action carry a greater risk for withdrawal symptoms (including seizures and rebound insomnia) than do agents with longer half-lives.¹¹ Gradual tapering of the BZ by no more than 10% of the total daily dose in 5- to 7-day intervals is recommended in patients who have been taking BZs for a prolonged period.¹¹ Elderly patients, who may metabolize these agents more slowly, are at an increased risk for unwanted side

effects, including falls. In addition, BZs should be used with caution in patients with a history of substance abuse.

Nonbenzodiazepines

In an attempt to minimize the unwanted effects of BZs, non-BZs such as zolpidem, zaleplon, and eszopiclone were developed for the treatment of insomnia. This class of drugs is chemically unlike the benzodiazepines, but the non-BZs do bind to a specific benzodiazepine receptor in the brain, thereby inducing sleep. Compared with the BZs, non-BZs are more selective for the α_1 subunit of the GABA_A receptor and, as a result, may be more specific for sedation with unwanted effects.^{11,12} Like the BZs, all non-BZs are categorized as schedule C-IV agents by the DEA.¹³⁻¹⁶

Use of BZs has declined since the first non-BZ, zolpidem, was marketed in 1993. Non-BZs currently available are zolpidem, zaleplon, and eszopiclone (Table 4).

Zolpidem (Immediate-release)—Indicated for the short-term treatment of insomnia, immediate-release zolpidem has sedative-hypnotic effects but no appreciable anticonvulsant or muscle-relaxant properties.^{12,13} The recommended bedtime dose of zolpidem is 10 mg in healthy adults and 5 mg in elderly, debilitated, and/or hepatically compromised patients.¹³ Exhibiting a usual onset of action within 30 minutes and an effect that can last up to 8 hours, zolpidem reduces sleep latency and can increase total sleep time. It has a bioavailability of 70% and is metabolized by cytochrome P450

TABLE 4 CHARACTERISTICS OF FDA-APPROVED SLEEP AGENTS^{4,8,11-18}

Generic Name	Brand Name	Class	Duration of Action	Elimination Half-life (h)*	Onset of Action (min)	Dosage (mg)*	Dosage (mg) in Elderly	Insomnia Indication	Generic Available
Estazolam	ProSom™	BZ	Intermediate	10-24	15-30	1-2	0.5-1	Sleep maintenance [†]	Yes
Flurazepam	Dalmane®	BZ	Long	74 ± 24	60-120	15-30	Not recommended	Sleep maintenance [†]	Yes
Quazepam	Doral®	BZ	Long	39	20-45	7.5-15	Not recommended	Sleep maintenance [†]	No
Temazepam	Restoril™	BZ	Intermediate	11 ± 6	45-60	7.5-30	7.5	Sleep maintenance [†]	Yes
Triazolam	Halcion®	BZ	Short	2.9 ± 1	15-30	0.125-0.25	0.125	Sleep onset [†]	Yes
Eszopiclone	Lunesta®	Non-BZ	Intermediate	6	30	2-3	1	Sleep onset and/or maintenance [‡]	No
Zaleplon	Sonata®	Non-BZ	Ultrashort	1	20	10-20	5	Sleep onset and/or maintenance [§]	No
Zolpidem	Ambien®	Non-BZ	Short	1.2-4	30	5-10	5	Sleep onset [†]	Yes
Zolpidem CR	Ambien CR™	Non-BZ	Short	1.2-4	30	6.25-12.5	6.25	Sleep onset and maintenance	No
Ramelteon	Rozerem™	Melatonin receptor agonist	Short	2-5	30	8	8	Sleep onset	No

FDA = Food and Drug Administration; BZ = benzodiazepine; CR = controlled release.

*In healthy adults.

[†]FDA approved for short-term (7-10 days) management of insomnia.

[‡]FDA approved for chronic treatment of insomnia.

[§]For sleep-maintenance insomnia; administer upon waking during the night.

(CYP3A4, mainly), CYP1A1, and CYP2D6 into three inactive metabolites that are renally excreted.¹³

Common adverse effects of zolpidem are headache (particularly during the discontinuation period), next-day residual drowsiness, fatigue, dizziness, and residual daytime sedation.¹¹⁻¹³ Non-CNS-related adverse effects include gastrointestinal upset and skin rash. At recommended doses, zolpidem does not appear to adversely affect next-day psychomotor or cognitive function, and the potential for tolerance or withdrawal symptoms and rebound insomnia upon discontinuation appears to be minimal.²⁰⁻²²

Controlled trials using objective measures (ie, polysomnography) and/or subjective measures (ie, patient self-evaluations of sleep) of sleep have extensively evaluated zolpidem in patients with primary insomnia.^{12,20-23} Several studies have demonstrated improved sleep latency and sleep duration with nightly administered zolpidem for up to 3 months, with no rebound insomnia or withdrawal symptoms after discontinuation.^{12,21} However, these findings have not been consistent. Some studies have shown that zolpidem did not differ significantly from placebo in reducing the number of awakenings, that the effects of zolpidem may decrease with long-term use, and that withdrawal symptoms and rebound insomnia can occur after discontinuation.^{12,22} In an attempt to overcome the development of tolerance and dependence in patients who require long-term sedative-hypnotic use, the continuous use of zolpidem was compared with intermittent administration (ie, 5 consecutive nights of zolpidem followed by 2 nights of placebo per week).²⁴ Similar improvements in sleep latency, total sleep time,

overall quality of sleep, and tolerability were seen with both dosing strategies.

Two large, randomized controlled trials (RCTs) evaluated the subjective effects of zolpidem in elderly patients with chronic insomnia.^{25,26} No consistent effect of zolpidem 5 mg on patient-reported number of awakenings after sleep onset was found in a 4-week study of more than 300 patients aged ≥ 60 years.²⁵ No evidence of tolerance or rebound insomnia was reported upon zolpidem discontinuation. By contrast, in a 2-week study of more than 500 patients aged ≥ 65 years, zolpidem 5 mg, compared with placebo, significantly reduced patient-reported number of awakenings.²⁶ Rebound insomnia was seen on discontinuation.

Zolpidem (Extended-release)—Extended-release zolpidem is FDA indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.¹⁴ The bi-layered tablet allows zolpidem to be delivered in two stages. The first layer dissolves immediately to induce sleep, whereas the second layer is released more gradually to improve sleep maintenance. To date, no studies have compared the efficacy of extended-release zolpidem with that of the immediate-release formulation. The recommended bedtime dose of extended-release zolpidem is 12.5 mg for healthy patients and 6.25 mg for elderly, debilitated, and/or hepatically compromised patients.¹⁴ Extended-release zolpidem tablets should be swallowed whole, not divided, crushed, or chewed. Because of the rapid release of the first layer, extended-release zolpidem should only be taken immediately before bedtime. Despite the differences in

formulation, the pharmacokinetics and adverse events of the two zolpidem formulations are similar.^{13,14}

In a study comparing a 3-week administration of extended-release zolpidem 6.25 mg and placebo in more than 200 elderly patients (aged ≥ 65 years) with primary insomnia, zolpidem significantly decreased sleep latency and increased total sleep time.²⁷ No next-morning residual effects were noted; however, worsening of sleep for a single night after abrupt discontinuation of extended-release zolpidem was reported.

Zaleplon—Like other non-BZs, zaleplon selectively binds to the α_1 subunit of the GABA_A receptor.^{11,12} Zaleplon has sedative effects, but minimal anxiolytic, muscle relaxant, or anticonvulsant effects.^{11,15} Zaleplon is approved for use at bedtime when difficulty falling asleep is the primary complaint. Zaleplon can also be dosed later in the night (up to 4 hours before anticipated wake time) without producing residual sedation and next-day psychomotor or cognitive impairment in patients with sleep-maintenance insomnia.^{15,26} The recommended dose of zaleplon is 10 mg in healthy adults and 5 mg in elderly patients and in patients who have hepatic dysfunction.¹⁵ Zaleplon has a usual onset of action of 20 minutes and an ultra-short elimination half-life of ~ 1 hour. High-fat meals can interfere with absorption, delaying time of onset, and reducing peak plasma concentration. After absorption, zaleplon undergoes significant first-pass hepatic metabolism, mainly by aldehyde oxidase and to a lesser extent by CYP3A4. As a result, bioavailability of zaleplon is only 30%.¹⁵ Inactive metabolites are renally excreted.

Zaleplon has a favorable safety

profile and is well tolerated. The most commonly reported adverse effect is headache, which appears to be dose dependent.^{11,12,15} Though uncommon, CNS-related effects such as next-day residual drowsiness, paresthesias, incoordination, dizziness, hallucinations, and ataxia have been reported.^{11,15} Zaleplon, relative to zolpidem, is associated with less psychomotor and memory impairment.^{12,28,29} Studies evaluating the effects of zaleplon on sleep disturbances have shown improvements in sleep latency but have failed to show consistent improvements in sleep duration or total sleep time.^{12,30}

Zaleplon 5 mg and 10 mg, administered for 2 weeks, have been evaluated in two RCTs in elderly patients.^{26,31} One study showed that both doses, compared with placebo, significantly reduced patient-reported sleep latency.³¹ In the second study, only the 10-mg dose significantly reduced sleep latency compared with placebo.²⁶ No clinically significant rebound insomnia, tolerance, withdrawal symptoms, or effects on number of awakenings were observed.^{26,31}

Eszopiclone—Eszopiclone is the S-isomer of zopiclone, a well-studied agent that has been available in countries other than the United States for nearly 20 years.^{12,16} For eszopiclone, the degree of α_1 selectivity at the GABA_A receptor is greater than that for BZs but less than that for zolpidem and zaleplon.^{12,17} As a result, eszopiclone produces sedative-hypnotic, anticonvulsant, and tranquilizing effects.

Eszopiclone is FDA approved for improving sleep maintenance and sleep latency in patients with insomnia.^{16,17} This agent is appropriate for use in patients with chronic insomnia.¹⁶ The recom-

mended starting dose is 2 mg at bedtime for patients who can remain in bed for at least 8 hours.¹⁶ The dose may be increased to 3 mg at bedtime, based on patient response. For elderly patients, patients with severe hepatic dysfunction, and patients taking potent CYP3A4 inhibitors (eg, ketoconazole, clarithromycin, nelfinavir), the starting dose should be reduced to 1 mg at bedtime. Rapidly absorbed after oral dosing, eszopiclone has a usual onset of activity within 30 minutes and an elimination half-life of ~6 hours in healthy adults.¹⁶ Eszopiclone is extensively metabolized via hepatic oxidation and demethylation, with CYP3A4 and CYP2E1 also involved. Ingestion of eszopiclone with or shortly after a high-fat meal may delay absorption and subsequent induction of sleep by up to 1 hour.¹⁶ Eszopiclone is well tolerated, with the most commonly reported adverse events in studies being an unpleasant taste, headache, and dizziness.^{16,17,32}

Long-term (>6 months) studies of eszopiclone use, as compared with placebo, have demonstrated improvements in patient-assessed sleep onset, sleep maintenance, sleep quality, and total sleep time. Neither tolerance to the sedative-hypnotic effects of eszopiclone nor withdrawal symptoms upon discontinuation have been observed in studies evaluating up to 12 months of nightly dosing.^{17,32}

Two studies evaluating eszopiclone 2 mg, administered nightly over 2 weeks in elderly patients with chronic insomnia, showed that they experienced significant improvements in patient-reported sleep latency, awakening after sleep onset, and sleep efficiency.^{33,34} In addition, one study reported improvements in daytime alert-

ness, morning sleepiness, sense of well-being, and daytime ability to function.³³ The most commonly reported adverse effect in these studies was unpleasant taste.^{33,34}

Melatonin Receptor Agonist: Ramelteon

Unlike BZ-receptor agonists, ramelteon is a selective melatonin receptor agonist.¹⁸ Responsible for regulating circadian rhythm, melatonin is an endogenous hormone released from the pineal gland into the circulation in response to environmental light/dark signals.³⁵ The exact mechanism of action of melatonin on sleep is unknown but likely involves stimulation of various melatonin (MT) receptor subtypes. The MT1 and MT2 receptor subtypes appear to contribute to the regulation of the 24-hour sleep-wake cycle, whereas the MT3 receptors do not appear to play a role in modulating sleep.³⁵ Exogenous supplemental melatonin has a short duration of action and lacks selectivity for the MT1 and MT2 receptors.³⁵ Ramelteon, compared with melatonin, has a longer duration of action and higher selectivity and affinity for the MT1 and MT2 receptors, which may enhance its sleep-promoting properties.^{18,35}

Ramelteon is FDA approved for sleep-onset insomnia and significantly reduces sleep latency and increases total sleep time. The recommended dose of ramelteon is 8 mg orally within 30 minutes of going to bed.¹⁸ Ramelteon is rapidly absorbed and undergoes extensive first-pass hepatic metabolism via oxidation, glucuronidation, and CYP1A2 (and CYP3A4 to a lesser degree), thereby limiting absolute bioavailability to <2%. Ramelteon has a usual onset of

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action within 30 minutes and it has four main metabolites, all of which are more active than the parent compound. The elimination half-life of these metabolites ranges from 2 to 5 hours. Ramelteon should not be given with or immediately after a high-fat meal because of decreased absorption and delayed onset of action.¹⁸

Ramelteon is generally well tolerated; adverse effects commonly reported during clinical trials have included headache, somnolence, dizziness, nausea, fatigue, and exacerbated insomnia.^{18,36} Studies evaluating ramelteon for the treatment of chronic insomnia did not show next-day residual effects or withdrawal symptoms or rebound insomnia upon discontinuation.³⁶ Ramelteon has no abuse potential and is not limited to short-term use in patients with chronic insomnia.¹⁸

In a placebo-controlled study of elderly patients with chronic insomnia, ramelteon 8 mg was found to significantly and persistently reduce time to sleep onset (subjective reports) during 5 weeks of nightly treatment.³⁷ The incidence of adverse effects was low, with dizziness, taste disturbances, myalgia, and headache most commonly reported. In a randomized, 9-week, 3-period crossover study, elderly patients with chronic insomnia were administered placebo, ramelteon 4 mg, and ramelteon 8 mg in three treatment phases (each phase was separated by 5- to 12-day washout periods) for 2 consecutive nights.³⁸ Significant improvements in latency to persistent sleep, total sleep time, and sleep efficiency were observed with both ramelteon 4 mg and 8 mg compared with placebo. No adverse next-day psychomotor or cognitive effects were observed.³⁸

Trazodone

A significant proportion of patients with sleep disturbances have depressive symptoms, which may precede, occur independently of, cause, or result from insomnia.^{4,8} As a result, despite a lack of FDA approval, sedating antidepressants are often used to treat insomnia. Trazodone, a sedating antidepressant, is commonly used at dosages of 25-100 mg nightly to treat insomnia.³⁹ By comparison, when trazodone is used as an antidepressant, adult daily doses range from 150 to 600 mg (given in divided doses).⁴⁰ Low-dose trazodone has been found to be effective in treating sleep disturbances when used in conjunction with antidepressants such as selective serotonin reuptake inhibitors that produce a wakening effect.³⁹

Commonly reported adverse effects of trazodone 75-500 mg include blurred vision, constipation, dizziness, drowsiness, dry mouth, headache, hypotension, nausea, and vomiting.^{39,40} Rare yet more serious adverse effects include cardiac events (eg, syncope, exacerbation of ischemic attacks, torsade de pointes and other arrhythmias) and priapism.⁴⁰ Trazodone appears to be associated with decreasing efficacy over time and with rebound insomnia upon discontinuation.³⁹ Little data exist evaluating trazodone and other sedating antidepressants in nondepressed patients with insomnia. Trazodone should be used with caution, particularly in elderly patients and in patients with pre-existing cardiovascular disease.

Nonprescription/OTC Treatments

Availability of nonprescription products for the treatment of insomnia, including antihista-

mines, herbal products, and dietary supplements, allows for increased options for persons experiencing symptoms of insomnia, despite lack of concrete efficacy data. However, the easy accessibility, perceived safety, and low cost of these products encourage self-treatment and can delay attention by a healthcare professional and effective treatment. Like all medications, these OTC products are not without risk and pose a potential for toxicity through inappropriate dosing, drug interactions, or improper use.

Antihistamines—Although OTC antihistamines are commonly used as sleep aids, limited data support the use of these agents for the treatment of insomnia.^{4,8,10} Diphenhydramine and doxylamine are first-generation, centrally acting H₁-receptor antagonists with sedating properties.⁴¹ Diphenhydramine is the most widely used OTC antihistamine and can be found alone or in combination with an analgesic in OTC products marketed for the relief of insomnia. A few studies have shown evidence that first-generation H₁-receptor antagonists (including diphenhydramine) can cause sedation, but little evidence supports sustained improvement in sleep.^{41,42} In addition to their primary H₁-receptor activity, these antihistamines can also act at serotonergic, cholinergic, and central alpha-adrenergic receptors to varying degrees, resulting in substantial unwanted adverse effects.^{41,42} Second-generation antihistamines such as loratadine and cetirizine possess limited ability to cross the blood-brain barrier and are not suitable for the treatment of insomnia.⁴¹

Lipophilic properties allow diphenhydramine to cross the blood-brain barrier, however,

causing sedation.⁴¹ The recommended dose of diphenhydramine is 25-75 mg at bedtime.⁴² An increase in dose >75 mg does not produce a corresponding increase in sedation but does produce an increase in adverse effects. Dose-related residual morning sedation occurs commonly because of the drug's long elimination half-life.⁴² In addition, muscarinic-receptor antagonism produces anticholinergic effects (eg, dry mouth, dry eyes, urinary retention, constipation, blurred vision, delirium).⁴¹ Antihistamines may also cause dizziness, affect psychomotor performance, and lower seizure threshold in patients with epilepsy.⁴¹ Some reports indicate that tolerance to antihistamines' sedative effects, but not the unwanted adverse effects, can develop by day 4 of treatment—compromising their usefulness in treating insomnia.⁴² Use of antihistamines in patients sensitive to the adverse effects of these agents, particularly elderly patients, should be avoided.

Alternative Options—Many patients perceive herbal products and dietary supplements to be natural and safe alternatives to prescription drugs and other OTC products. Data supporting the safety and efficacy of such products are weak because studies have enrolled few subjects, are of short duration, and use varying doses and product formulations.⁴³ Pre-market evaluation and approval by the FDA are not required for herbal or dietary supplements unless claims are made for specific disease treatment or prevention. Herbal and dietary supplement products are considered “generally regarded as safe” (GRAS) unless proven otherwise.⁴⁴ Furthermore, because these products are marketed as supplements, manufacturing is not regulated by the FDA for quality of consistency,

and potency varies across manufacturers, formulations, and product lots.

Melatonin and valerian are commonly used as mild hypnotics, and evidence supports their use for insomnia in certain populations.⁴³⁻⁴⁵ Kava (kava kava, *Piper methysticum*) is best known for its anxiolytic properties but is often used as a sedative despite a lack of evidence of efficacy. Kava is considered unsafe because of reports of hepatotoxicity at recommended daily doses (70-280 mg at bedtime); practitioners should discourage its use.⁴³ L-tryptophan, an amino acid precursor to melatonin and serotonin, was removed from the US market in 1990 because of numerous case reports of eosinophil-myalgia syndrome (EMS).⁴³ However, the by-product of L-tryptophan, 5-hydroxy-tryptophan, is still available. Neither product has proved to be effective for insomnia and should not be recommended because of possible contamination leading to EMS.⁴³ Not enough evidence supports the efficacy and safety of other natural products purported to have sedating properties (eg, chamomile, passion flower, coenzyme Q10, hops, lemon balm, lavender, skullcap) for the treatment of insomnia.⁴³

Melatonin, not to be confused with melatonin receptor agonists, is involved in the modulation of the circadian rhythm. However, the use of melatonin for the treatment of insomnia is not supported by rigorous data.⁴³ Melatonin is considered GRAS in recommended doses (0.3-5 mg administered 30-120 minutes before bedtime) for short-term use and is likely safe when used orally for up to 2 years.⁴³ Next-morning residual effects are uncommon.⁴³ Safety of melatonin has not been estab-

lished in children <18 years, and the use of melatonin in this population is not recommended.⁴³ Caution is advised in patients with vascular disorders and in those taking immunosuppressive therapy because melatonin may cause vasoconstriction and enhance immune functioning.⁴³ High doses of melatonin (75-300 mg/day) can inhibit ovulation and contribute to infertility in women.³⁵ Case reports raise concerns about increased risk of bleeding, seizures, psychotic symptoms, and disorientation with melatonin overdose.⁴³ Caution should be exercised in patients taking warfarin or other agents that affect coagulation and platelet aggregation.

Conclusion

Insomnia is a prevalent condition associated with major morbidity. Untreated insomnia has substantial economic and health-related consequences. Improving both sleep-onset and sleep-maintenance disturbances—without adverse effects on measures of daytime function—is an important therapeutic goal in the treatment of insomnia.

Treatment of sleep disturbances involves both nonpharmacologic and pharmacologic approaches. Nonpharmacologic strategies for the treatment of insomnia may improve insomnia, but treatment response can vary and these strategies remain underused. BZs have been well studied and are commonly used in the pharmacologic treatment of insomnia but are associated with substantial limitations. Non-BZs offer hypnotic efficacy similar to that of the BZs and, as a class, may offer decreased risk of long-term tolerance and a lower risk of next-day hangover effects. Eszopiclone is the only non-BZ evaluated in trials lasting 6-12

months. Although trazodone, an antidepressant, and certain OTC products are widely used as soporific agents, few data are available regarding their safety and efficacy in treating insomnia; caution is advised. Ramelteon, a melatonin receptor agonist, is another option for the treatment of insomnia. Further clinical experience is necessary to determine whether this agent offers any major advantages over the non-BZs.

In general, nonpharmacologic and pharmacologic interventions used by persons with sleep disturbances should address particular underlying causes. Pharmacotherapy should be used with appropriate caution, at minimal effective doses, and for the minimal duration required. ■

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Caring for Organ Transplant Recipients

Raquel Marie Mahidashti, FNP-C

This article will increase nurse practitioners' (NPs') awareness of the variety of complications and problems that may arise in patients who have undergone organ transplantation and will provide an overview of treatment options. Prevention/management of cardiovascular disease (CVD), diabetes, infection, and malignancy, among other conditions, is essential in caring for adult transplant recipients. NPs are well suited to manage these conditions in collaboration with members of the organ transplant team.



Recipients of solid organ transplants are surviving longer than ever before, thanks to advances in surgical techniques, organ preservation, transplant team coordination, and immunosuppressive therapy.¹ The number of patients receiving organ transplants has been increasing too.² According to the United Network for Organ Sharing (UNOS) national database, 28,112 solid organ transplants occurred in the United States in 2005, 28,931 transplants occurred in 2006, and 19,249 transplants have occurred between January 1, 2007, and August 30, 2007.³ Near the end of 2007, a total of 98,031 persons were on the waiting list for organs.³ Expansion in donor candidate criteria for deceased and living donors has also contributed to the increase in the number of organ transplants in this country.³

As the number of organ recipients, as well as the survival rate fol-

lowing organ transplantation, increases (Table 1), patients will be at risk not only for complications specific to the organ transplant process, but also for conditions that can affect anyone who ages.³ Transplant recipients face a variety of metabolic complications—as a function of the transplant process, aging, or both—including diabetes, dyslipidemia, obesity, arterial hypertension, renal disease, and cancer.⁴ Development of CVD after transplantation has particularly serious consequences, including reduced graft function, increased risk of graft loss,⁵ and reduced survival (CVD is the main cause of death in organ transplant recipients).⁶

Organ transplant recipients must take immunosuppressive agents to prevent graft rejection. In general, the development of infections and malignancies depends more on the overall immunosuppressive load than on the particular agent(s) administered to prevent rejection.⁶ Use of long-term immunosuppressives also increases the risk of developing CVD because these agents can cause fluid retention and can impair glucose metabolism. Patients' long-term quality of life (QoL) depends on early recognition and management of post-transplant comorbidities.⁷

When assessing the success of organ transplantation, many studies have focused on short-term survival of the patient and of the graft. However, onset of new signs and symptoms (S/S), S/S-related distress, QoL, and long-term survival are also critical elements of the post-transplant process. After transplantation, organ recipients must make many lifestyle changes, including taking immunosuppressives on a daily basis, monitoring for S/S related to the drug regimen, and keeping track of new-onset

TABLE 1 ORGAN TRANSPLANT 5-YEAR SURVIVAL³

Organ	5-Year Survival (N)	5-Year Survival (%)
Kidney	29,863	82%
Liver	9347	71%
Heart	5241	70%
Lung	1519	46%
Intestine	36	47%

Number and percentage of adults who received an organ transplant in 1997.

S/S, including those of infection and organ rejection.

The Report of the 2005 US Preventive Service Task Force,⁸ the 2006 Institute for Clinical Systems Improvement,⁹ and the National Cholesterol Education Program (NCEP)¹⁰ are useful resources for NPs because they provide guidelines that reflect healthcare quality improvement initiatives. Also, the incidence of new-onset diabetes after heart, liver, or kidney transplantation has been systematically reviewed.¹¹⁻¹⁴ In particular, the 2003 International Consensus Guidelines (ICG) were developed to help clinicians identify and manage new-onset diabetes in post-transplant recipients.¹⁴

Risk of Organ Rejection

The risk of organ rejection is highest after the first 3 months post-transplant and remains a threat throughout a patient's life. A standard immunosuppressive regimen consists of tacrolimus/mycophenolate mofetil or cyclosporine/mycophenolate mofetil plus a corticosteroid. Maintenance immunosuppressive therapy is required indefinitely, with blood levels of these agents monitored by the transplant team on a routine basis. The length of therapy and type of immunosup-

pression depends on the underlying diagnosis. Table 2 lists common adverse events associated with the use of immunosuppressants and corticosteroids.¹⁵ If, for any reason, patients are unable to take medications to manage or treat pre-existing conditions/diseases or those that develop post-transplantation, on a strict schedule or by the specified route (eg, by mouth), NPs should contact the transplant center team about alternatives.

Primary Care Issues for NPs

CVD—Too few practitioners follow guidelines for CVD prevention, even in the non-transplant setting.¹⁶ The incidence of CVD is about 10 times higher in kidney transplant recipients than in the general population.¹⁷ Furthermore, CVD is responsible for 40% of all deaths following *successful* kidney transplantation.¹⁷ As in the general population, several factors, including hypertension, dyslipidemia, and diabetes, increase CVD risk in transplant recipients.⁵ NPs can use a gender-specific tool such as the Framingham Risk Score (FRS) to determine a patient's 10-year risk of experiencing a coronary event based on age, total cholesterol, high-density lipoprotein cholesterol (HDL-C), blood pressure

TABLE 2 ADVERSE EVENTS ASSOCIATED WITH IMMUNOSUPPRESSANTS AND CORTICOSTEROIDS¹⁵

Body System	Adverse Event
Cardiovascular	Arrhythmias Hyperlipidemia Hypertension
Central nervous system	Anxiety Confusion Insomnia Mood change/agitation Psychosis
Dermatologic	Acne Diaphoresis Ecchymosis Hirsutism Impaired wound healing Petechiae Thin skin
Endocrine/metabolic	Cushing syndrome Hyperglycemia Sodium and water retention
Gastrointestinal	Gastritis Increased appetite Nausea, vomiting, diarrhea Peptic ulcers
Hematologic	Leukocytosis
Neuromuscular/skeletal	Arthralgia Headaches Impaired growth Osteoporosis Seizures Skeletal muscle weakness Tremors
Ocular	Cataracts Glaucoma
Respiratory	Epistaxis

(BP), diabetes status, and smoking status.¹⁰ The NCEP's Risk Assessment Tool, which generates an FRS, is available at <http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=pub>¹⁸

New-onset Diabetes—The cumulative incidence of new-onset diabetes in heart transplant recipi-

ents may reach 32% at 5 years, which is similar to that reported in kidney and liver transplant recipients.¹⁹ One study showed that 10-year survival in transplant recipients with diabetes was 40%, versus 58% in transplant recipients without diabetes.²⁰ Risk factors for new-onset diabetes after kidney

and liver transplantation include black or Hispanic ethnicity, family history of diabetes, age >40 years, glucose intolerance before transplantation, use of immunosuppressives, metabolic syndrome (low HDL-C, elevated triglycerides [TG], hypertension), hepatitis C infection, use of a cadaveric kidney, and obesity.²¹

More about the ICG. The aim of the ICG is to reduce the incidence and impact of new-onset diabetes after transplantation by providing appropriate management strategies for transplant recipients.¹⁴ The ICG uses definitions outlined by the American Diabetes Association, the World Health Organization, the International Diabetes Federation, and the American College of Endocrinologists. All organ transplant candidates, regardless of diabetes status, should undergo regular fasting plasma glucose (FPG) testing before and after transplantation to screen for abnormal glucose regulation (Figure).¹⁹ During the first month post-transplantation, patients should undergo FPG testing at least once weekly. If an intermediate FPG level is detected (6.1-6.9 mmol/L [110-125 mg/dL]), oral glucose tolerance testing (OGTT) is recommended. After the first month post-transplantation, all patients should undergo FPG testing at 3, 6, and 12 months, and then annually thereafter.

Effect of immunosuppressives.

The transplant team will closely monitor patients for glucose impairment following transplantation, particularly during the first 6 months. Once patients are stabilized, the primary care practitioner will likely resume routine monitoring. Detection of impaired glucose tolerance while a patient is on an immunosuppressive regimen

should signal NPs to initiate a discussion with the transplant team for possible modification of the regimen. NPs should also educate patients about S/S of a hyperglycemic crisis, including polydipsia, polyuria, weight loss, blurred vision, fatigue, weakness, and nocturnal enuresis.

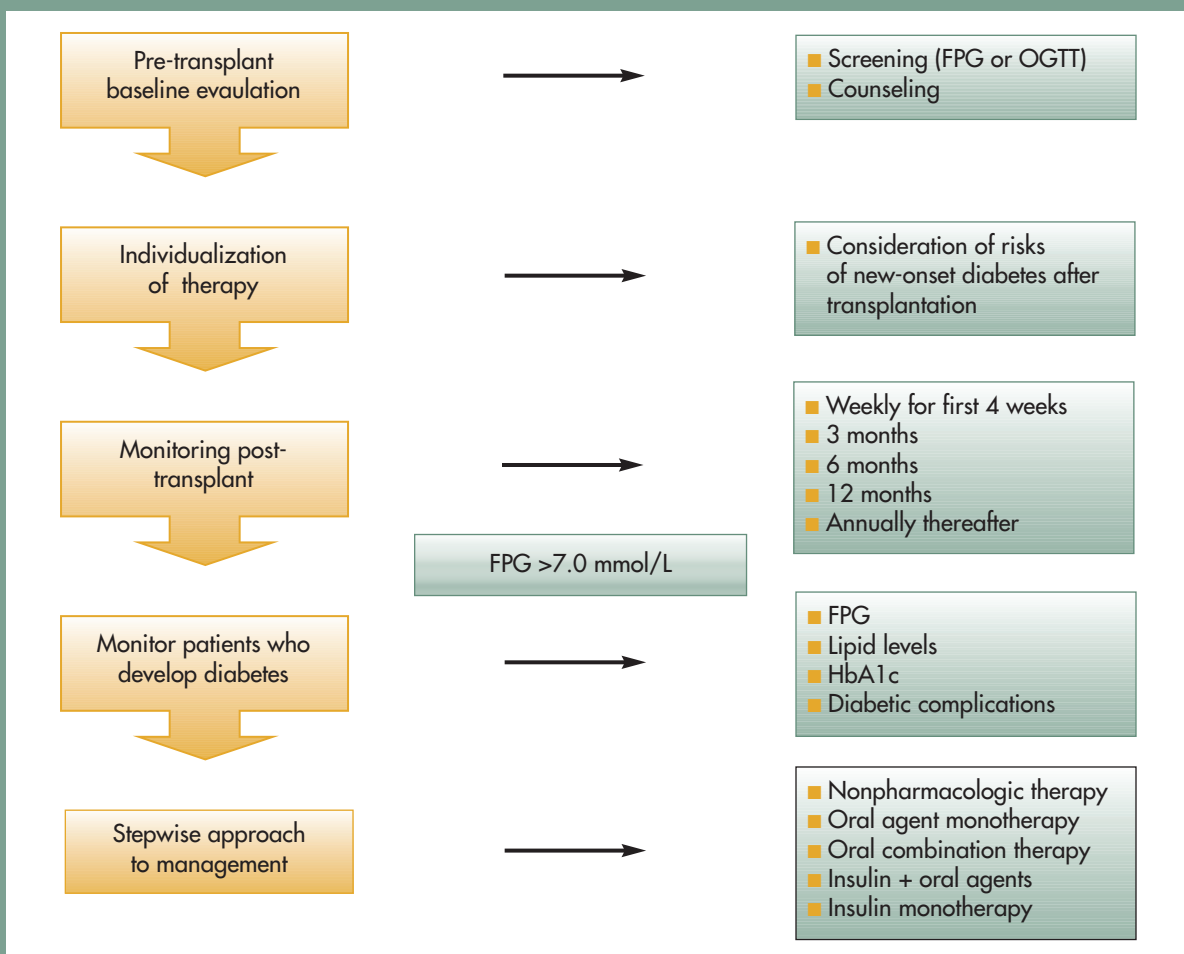
Use of hypoglycemics. All classes of hypoglycemic medications can be used in transplant recipients; in some cases, a combination of medications is needed to achieve tighter glycemic control.

Liver transplant recipients on ribavirin and interferon for hepatitis C need to use insulin to control blood glucose because of a potentially adverse interaction between oral hypoglycemics and the drugs used to treat hepatitis C and because the liver's ability to metabolize orally administered drugs is compromised.

Hypertension—Hypertension develops in up to 65% of liver transplant recipients.²² Elevated BP is particularly dangerous, and should be treated aggressively, in

transplant recipients with pre-existing or new-onset diabetes. The ICG goal for patients with new-onset diabetes is a BP of 130/80 mm/Hg or lower.¹⁴ According to the Seventh Report of the Joint National Committee, morbidity and mortality are increased in patients with diabetes if systolic BP exceeds 130 mm/Hg.²³ Immunosuppression itself is correlated with an adverse effect on BP (Table 3), making treatment of hypertension in transplant recipients even more challenging.^{24,25}

FIGURE. | MANAGEMENT OF NEW-ONSET DIABETES AFTER TRANSPLANTATION¹⁹



FPG = fasting plasma glucose; OGTT = oral glucose tolerance test; HbA1c = glycosylated hemoglobin.

As recommended by the 2003 International Consensus Guidelines. Adapted from Marchetti P. New-onset diabetes after transplantation. *J Heart Lung Transplant.* 2004;23(5 suppl 1):S194-S201.

TABLE 3 EFFECTS OF IMMUNOSUPPRESSION ON BLOOD PRESSURE^{24,25}

Drug	Effect on Blood Pressure
Corticosteroids (eg, prednisone, methylprednisolone)	Increases
Tacrolimus	Increases
Cyclosporine	Increases
Mycophenolate mofetil	No direct effect
Azathioprine	No direct effect
Sirolimus	No direct effect

Renal Complications—Renal insufficiency and chronic renal failure are major complications after transplantation, even in non-renal transplant recipients.²⁶ The incidence of chronic kidney disease (CKD) ranges from 10% to 83% in recipients of solid organ transplants.²⁶ The longer transplant recipients survive, the greater the risk of developing renal disease related to an increased exposure to nephrotoxic conditions.²⁷ The 5-year risk of CKD after transplantation of non-renal organs ranges from 7% to 21%.²⁸ Added to this risk is the natural decline in renal function after the fourth decade of life.¹³ Common causes of renal dysfunction are hypertension, dyslipidemia, and use of nephrotoxic immunosuppressive agents.⁷ In one study, the proportion of cyclosporine-treated heart transplant recipients with normal renal function was 55% at 6 months, 17% at 12 months, 4% at 24 months, and 0% at 36 months.⁷ Table 4 lists antihypertensive agents that are renoprotective. Other antihypertensives can be used when indicated, but NPs are advised to contact patients' transplant center before changing or adding any medications.

Dyslipidemia—An elevated level of low-density lipoprotein

cholesterol (LDL-C) is one of the strongest risk factors for CVD development.²⁹ Likewise, a low HDL-C and a high level of very-low-density lipoprotein cholesterol are CVD risk factors.²⁹ Dyslipidemia develops in 60%-80% of liver, heart, or kidney transplant recipients.²⁹ NPs can use the NCEP's Third Adult Treatment Panel (ATP III) guidelines to manage dyslipidemia and reduce CVD risk in this patient population. The ATP III guidelines stratify patients into low, medium, and high risk for developing CVD; risk stratification depends on other factors in addition to lipid profile. Among transplant recipients, those who receive a kidney are at highest CVD risk.¹⁰ For patients in the high-risk category, the target LDL-C level is 70 mg/dL.³⁰ Recommended treatment for dyslipidemia in trans-

plant recipients includes the use of statins and fibrates. Also, switching from cyclosporine- to tacrolimus-based therapy can safely and dramatically improve dyslipidemia.³¹ Another option is to reduce or withdraw steroids if possible.^{31,32} According to ICG, organ transplant recipients should receive aggressive lipid-lowering therapy in accordance with NCEP guidelines.^{10,14} Similarly, Munoz and Elgenaidi recommend that liver transplant recipients undergo yearly CVD screening via measurement of serum cholesterol, TG, and lipoproteins, and assessment for other risk factors.³⁴

Infection—Organ transplant recipients are at risk for infection during the early transplant phase, the side-effect management phase, and the maintenance phase (Table 5).³⁵ The risk of infection after solid-organ transplantation depends on several factors, including the degree of immunosuppression, the type of organ transplanted, technical or surgical complications, the need for additional anti-rejection therapy, environmental exposures, and time frame after transplantation.³⁵

Infections occurring during the early transplant phase (month 1 postoperatively) are similar to those occurring in non-transplanted postsurgical patients, and include urinary tract infection, bacterial or

TABLE 4 RENOPROTECTIVE MEDICATIONS

Drug	Renal Protective Effect
Angiotensin-converting enzyme inhibitors: benazepril, captopril, enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, trandolapril	In patients with diabetes, may improve microalbuminuria; slows progression of renal disease
Angiotensin-II receptor blockers: candesartan, irbesartan, losartan, olmesartan, valsartan	Improves microalbuminuria

Gynazole Insert

Gynazole Insert

fungal wound infection, pneumonia, and sepsis related to intravascular or indwelling catheters.³⁶ Transplant recipients may be placed on a prophylactic antibiotic regimen such as double-strength trimethoprim/sulfamethoxazole. During the side-effect management phase (months 2-6 postoperatively), opportunistic infections classically associated with transplantation occur;³⁷ these infections are most commonly caused by cytomegalovirus (CMV), *Pneumocystis jirovecii* (*carinii*), *Aspergillus* species, *Nocardia* species, toxoplasmosis, *Listeria monocytogenes*, and fungi (candidiasis and mucormycosis).³⁷ Other pathogens, including Epstein-Barr virus, CMV, hepatitis B virus, hepatitis C virus, varicella zoster virus, human herpesvirus type 6, and human immunodeficiency virus (HIV), can be reactivated during this vulnerable period, when immunosuppression is at its peak.³⁵⁻³⁷ For the most part, reactivated viruses should be managed pharmacologically by the transplant center team. Beyond 6 months, infections are rare in patients with normal graft function.³⁶ In fact, the most common infections occurring during this period are those seen in

the general community.³⁵

Transplant recipients who experience multiple rejection episodes requiring additional anti-rejection medications are at even higher risk of developing opportunistic infections because of their immunocompromised status. Live vaccines are absolutely contraindicated while patients are on long-term immunosuppressive therapy. However, influenza and pneumonia immunizations should continue as indicated.

With the prevalence of communicable diseases such as the common cold, hepatitis, and HIV infection, NPs must educate their patients about preventive and self-protective measures, including practicing good hand-washing habits and safe sex, avoiding contact with persons who are ill, and avoiding risky behaviors.

Cancer—Compared with the general population, transplant recipients have a 50 to 100 times greater risk of developing skin cancer.³⁸ The presence of human papillomavirus (HPV) in combination with exposure to ultraviolet radiation (the most common risk factor for skin cancer) and the degree and

length of immunosuppression are important factors in the development of squamous cell carcinoma and, to a lesser extent, basal cell carcinoma.³⁸ After transplantation, patients should be seen by a dermatologist every 3-6 months. Patients must be counseled to avoid prolonged sun exposure; to wear sunscreen with a sun protection factor of ≥ 35 ; to routinely check their own skin, seeking help from a partner for hard-to-see areas; and to promptly report any new and/or suspicious lesions.

The incidence of all cancers is greater in immunocompromised patients; therefore, annual screening for breast, cervical, colorectal, and prostate cancers is vital. Yearly screening for breast cancer (mammography and clinical breast examination) is recommended in women aged ≥ 35 years.⁸ Colorectal cancer screening is recommended for all persons aged ≥ 50 years, with annual fecal occult blood testing or colonoscopy or both; depending on family history, patients should be screened at least every 10 years.⁸ Patients who have anogenital HPV infection have a 20-100 times higher risk of developing cervical

TABLE 5 OCCURRENCE OF INFECTIONS AFTER TRANSPLANTATION³⁵

Transplant Phase	Infections	Recommendations
Early (1 month post-op)	<ul style="list-style-type: none"> ■ Increased risk for bacterial infections ■ Common nosocomial infections ■ Intra-abdominal infections (30% of organ transplant recipients) 	<ul style="list-style-type: none"> ■ Patients are seen weekly during month 1, then every 2 weeks
Side-effect Management (2-6 months post-op)	<ul style="list-style-type: none"> ■ Increased risk of infection, including opportunistic infections, because of the effects of corticosteroids and immunosuppressive medications 	<ul style="list-style-type: none"> ■ Patients are seen every 3 months or more frequently as needed
Maintenance (6+ months post-op)	<ul style="list-style-type: none"> ■ Preventive health maintenance ■ Common community-acquired infections ■ Opportunistic infections (rare) 	<ul style="list-style-type: none"> ■ Maintain follow-up with transplant team once yearly

or anogenital cancer, so they should also undergo frequent testing for these diseases.³⁸

Sexuality and Reproduction—Transplant recipients may have difficulty with sexual functioning and lower sexual self-esteem.³⁹ In a study by Hricik et al, 61% of male and female respondents reported adverse effects related to loss of interest or ability to perform or respond sexually, and more than 50% reported adverse effects related to their physical appearance (eg, changes in body shape, unusual hair growth).⁴⁰ Asking specific questions about the nature and extent of patients' sexual difficulties can help guide NPs' assessment and their design of interventions.³⁹ As reproductive-aged female transplant recipients return to their baseline health status, they must be counseled on family planning, birth control, and sexually transmitted diseases, and encouraged to seek yearly Pap smears, breast exams, and mammograms.

Osteoporosis—The most rapid loss of bone density appears to occur in the first 3 months after transplantation.⁴¹ All patients should take a supplement containing calcium (1000-1200 mg/day) and vitamin D. Patients should avoid using loop diuretics (eg, furosemide, torsemide, bumetanide), which can adversely affect bone health by increasing renal calcium excretion. By contrast, thiazide diuretics (eg, hydrochlorothiazide) can increase renal calcium absorption. Patients with osteopenia or osteoporosis who need diuretic therapy would therefore benefit from the use of thiazide diuretics,²¹ and should take a bisphosphonate (eg, alendronate, risedronate) to treat corticosteroid-induced osteoporosis. Bone scans are indicated at baseline (ie, before

transplantation) and every 3-5 years afterward, depending on each patient's treatment course.

Use of Over-the-counter (OTC) Medications—Among organ transplant recipients, 46%-80% will survive ≥ 5 years after the transplant procedure.² As more transplant recipients live longer, they are likely to experience common maladies such as aches, pain, constipation, diarrhea, headache, and flu-like symptoms. Therefore, NPs should anticipate questions about the use of OTC medications and supplements. Many OTC, complementary, and alternative medications are harmful for transplant recipients. If in doubt, NPs should contact the transplant center team for further direction.

Transplant recipients must avoid nonsteroidal anti-inflammatory drugs because of their potentially nephrotoxic effects.⁴² Use of low-dose aspirin for prevention of CVD and cerebrovascular events appears to be safe, but patients must be carefully monitored for gastritis and gastrointestinal (GI) bleeding, especially if aspirin is used concurrently with prednisone.⁴²

Bulk-forming laxatives are fairly safe, with side effects limited to the GI tract. These laxatives mimic the physiologic method of fecal evacuation and can safely be used longer than other laxatives.²⁴ Short-term stool softeners such as docusate sodium, docusate calcium, and docusate potassium can be useful in some patients, but NPs need to check for possible hyperkalemic effects of the latter two medications. Loperamide, an antidiarrheal agent, can be used safely in transplant recipients, but NPs should monitor them for urinary retention, dysuria, and GI reactions. Antihistamines are generally safe, but patients should be monitored for sedative

and anticholinergic effects. Dextromethorphan, guaifenesin, and codeine are safe for cough.²⁴

Mental Disorders and Non-adherence Concerns—Compared with the general population, transplant recipients are at greater risk for mental disorders owing to long-term use of immunosuppressive agents, the long-term illness itself, and the use of certain antiviral medications. Anxiety, insomnia, and depression frequently occur despite excellent function of the transplanted organ itself.⁴³ Patients with untreated depression are less likely to adhere to their therapeutic regimens, which in turn can increase the risk for graft rejection or infection. Non-adherence to therapeutic regimens is also associated with substance abuse, which may be difficult to identify.

Routine screening for depression, alcohol/substance abuse, and life-changing events, followed by appropriate treatment and support to promote effective coping strategies, is essential for optimal patient outcomes. Long-term monitoring of transplant recipients' adherence to their therapeutic regimens is as important as monitoring their clinical outcomes. Pharmacologic management of depression is often necessary; a low-dose selective serotonin reuptake inhibitor is a prudent choice for this patient population.⁴⁴ If pharmacotherapy is not feasible, mindfulness-based stress reduction techniques are recommended.⁴³

Patient education regarding the importance of adherence to the therapeutic regimen is most effective if it is consistent and individualized, and takes into account each patient's cognitive, educational, developmental, and intellectual capacities.⁴⁵ Other options for enhancing adherence include self-

medication education and computer-based learning tools. NPs should contact patients' transplant team with questions or concerns. Random urine toxicology screens are necessary if alcohol or illicit drug use is suspected.

Obesity, Inactivity, and Smoking—Long-term corticosteroid use can lead to muscle weakness and fatigue, and ultimately to physical deconditioning. In a study assessing QoL after liver transplantation, van Ginneken et al found that, compared with the general population, transplant recipients had impaired cardiorespiratory fitness.⁴⁶ Patients' feelings of fatigue led to decreased physical activity and decreased physical fitness, leading to further deterioration and greater fatigue. Future randomized controlled trials are needed to determine whether a rehabilitation program to improve physical fitness (particularly cardiorespiratory fitness) will result in improved physical and social functioning and vitality and reduced pain.⁴⁶ Although regular, low-impact aerobic exercise is not contraindicated in this patient population, NPs should refer patients to a cardiologist for clearance before recommending an exercise regimen.

Tobacco use is associated with graft loss, higher mortality, lower QoL, and lesser benefit gained from surgical interventions.⁴⁷ Further evidence indicates that cigarette smoking may contribute to poor graft function, CVD, and the development of secondary malignancies after transplantation.^{48,49} The US Surgeon General recommends a systematic, repetitive approach to assess tobacco use and provide treatment and follow-up appropriate to patients' readiness to quit smoking and strategies for NPs to facilitate

smoking cessation.⁵⁰ NPs should not assume that transplant recipients who smoke have been counseled about smoking cessation, and they should provide encouragement for remaining abstinent.

Clinical Pearls

Before qualifying as an organ recipient, prospective candidates are evaluated by the transplant team to determine potential problems with adhering to their drug regimens. In general, patients awaiting organ transplants are seriously ill, and most have a long history of complications secondary to organ failure. Most patients are fearful and anxious about the transplant process. To simplify the transplant process, most listed patients are advised to check with the transplant team before starting any new diets, vitamins, supplements, drugs, alternative medications, or travel, or making changes in recommended follow-up intervals or lifestyle patterns.

After transplantation, patients may hesitate to resume primary care services, even from their referring practitioner, because of the bonds and agreements created early in the transplant evaluation process. NPs can "reclaim" their referred transplant recipients by

initiating follow-up, especially if patients are due for annual level 1 services. Table 6 lists level 1 preventive services that practitioners and care systems must deliver, based on best evidence.⁹

Patients may need or wish to contact their transplant coordinator to verify their re-affiliation with their NP—this action represents a favorable sign of patients' desire to adhere to their treatment plan. To reinforce patients' trust, NPs should include the transplant coordinator in patients' continued care by sending periodic office visit notes and calling with questions or to discuss new problems. Most transplant recipients can recite their transplant coordinator's full name and their main and alternate contact numbers. By agreeing to communicate with the transplant team on patients' behalf, NPs can optimize care and patient outcomes. NPs should also consult with a pharmacologist or pharmacist (or a reliable drug reference manual) before starting new medications in patients on immunosuppressive therapy. Many potential drug interactions may occur with any drug regimen; attending to these risks can avoid potential adverse reactions.

TABLE 6 LEVEL 1 PREVENTIVE SERVICES⁹

- | | |
|---------------------------------------|------------------------------------------------------------------------|
| ■ Aspirin chemoprophylaxis counseling | ■ Influenza immunization |
| ■ Breast cancer screening | ■ Pneumococcal immunization |
| ■ Calcium chemoprophylaxis counseling | ■ Problem drinking screening and brief counseling |
| ■ Cervical cancer screening | ■ Tobacco use screening and brief intervention |
| ■ Chlamydia screening | ■ Total cholesterol and high-density lipoprotein cholesterol screening |
| ■ Colorectal cancer screening | ■ Vision screening |
| ■ Hypertension screening | |

Conclusion

As more individuals undergo successful organ transplantation and survive longer, NPs can expect to see a greater number of them in their practice. Primary prevention, heightened vigilance, and avoidance of potential complications will improve outcomes. In accordance with providing competent, comprehensive, and compassionate health care, NPs in the primary care setting provide a valuable service for transplant recipients. ■

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Urinary Tract Infections in the Elderly: Symptomatology and Prevention



Kelly Krause, MS, RN, APRN-BC;
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This article discusses the importance of prompt and accurate diagnosis of urinary tract infection (UTI) in the elderly, the risk factors and atypical presentations that place the elderly at a greater disadvantage in terms of making an accurate UTI diagnosis, UTI treatment, and ways in which nurse practitioners (NPs) can limit the occurrence of UTIs in this patient population.

Making an accurate and prompt diagnosis of UTI in an elderly patient is challenging because such a patient may present with complex clinical symptoms—or no symptoms at all.

Urinary tract infections constitute a major health problem in the elderly.¹ In this population, UTIs can quickly escalate to urosepsis, which has a mortality rate of up to 60%.² UTIs, the leading cause of gram-negative sepsis,³ may have other serious complications such as shock, abscess formation, disseminated intravascular coagulation, acute respiratory distress syndrome, and chronic renal insufficiency.^{1,4-7} Making an accurate and prompt diagnosis of UTI in an elderly patient is challenging because such a patient may present with complex clinical symptoms—or no symptoms at all.^{1,4-7}

As people age, UTI risk increases significantly.⁸ In fact, UTIs are the most common infection in the geriatric population,^{4,9} including elderly patients residing in long-term care facilities (LTCFs).¹⁰ The Centers for Disease Control and Prevention has reported that the urinary tract is the most common site for nosocomial infections, and that UTIs represent >40% of institutionally acquired infections.¹¹ Sixty percent of all bacteremic UTIs in the elderly population occur in hospitals or LTCFs.⁵ Among elderly women with a UTI, 60% experience a recurrence within 10 years and 10% have ≥ 10 UTIs during the rest of their lifetime.⁷

Case Study

Ms Anne Knight (a pseudonym) is a 66-year-old African-American woman with a history of diabetes mellitus, hypertension, cerebrovascular accident, and advanced multiple sclerosis (MS) that necessitates an indwelling Foley catheter. She also has right-sided hemiplegia related to a prior cerebrovascular accident (CVA). She has been residing in an LTCF for the past 5 weeks and has been in stable condition. She has been in no apparent distress, speaks coherently, and has stable vital signs. Her reported height is 5'3", her weight has been consistent at 155 pounds, her daily blood glucose readings range from 88 to 254 mg/dL, her glycosylated hemoglobin is 6.8, and her daily blood pressure (BP) readings range from 128/78 to 146/92 mm Hg. She requires assistance with activities of daily living (ADLs). She is usually pleasant and cheerful, and communicates well with the nursing staff. The nurse covering the night shift informs the NP that Ms Knight has been experiencing increased somnolence and confusion. The last blood glucose reading was 330 mg/dL. Upon assessing Ms Knight, the NP finds her lethargic but arousable to stimuli. Her temperature is 100.2° F, her BP is 92/60 mm Hg, and her pulse rate is 102 beats/minute. The differential diagnosis (DDx) includes hypoglycemia, pneumonia, sepsis, pulmonary embolism, CVA, and UTI.

Asymptomatic Bacteriuria

The overall prevalence of asymptomatic bacteriuria, defined as $\geq 100,000$ colony-forming units (CFUs) per mL of urine, in persons aged ≥ 70 years is 20% in the community and 50% in LTCFs.^{6,10} Prevalence of asymptomatic bacteriuria by gender in the elderly is 15%-30% for men and 25%-50% for women.⁹ Older adults with the greatest functional impairment, especially those with dementia and urinary and bowel incontinence, are the most likely to have asymptomatic bacteriuria.⁹

In the absence of urinary tract symptoms such as acute dysuria, body temperature $>100^{\circ}\text{F}$, new or worsening onset of urinary frequency/urgency, suprapubic pain, urinary incontinence, new costovertebral-angle tenderness, gross hematuria, or new-onset delirium,¹² elderly patients do not benefit from treatment of asymptomatic bacteriuria; in fact, treatment with antibiotics may be

harmful.^{13,14} Many clinical trials have established that antibiotics neither effectively treat asymptomatic bacteriuria^{1,10} nor enhance patient outcomes.^{7,12,15} Instead, such treatment contributes to an ever-increasing number of resistant organisms.

A positive urine culture finding and pyuria without urinary tract symptoms are non-diagnostic for UTIs in this population: 25%-50% of women and 15%-40% of men who live in nursing homes have chronic bacteriuria.⁶ In addition, 90% of patients with asymptomatic bacteriuria have pyuria, and 30% of patients without bacteriuria have pyuria related to other genital, bladder, prostatic, or renal causes.¹⁰ One study showed that 50% of women and 40% of men living in an LTCF had bacteriuria but did not have signs and symptoms (S/S) of a true UTI.¹² The Infectious Disease Society of America stated that "evaluation of potential symptoms of UTI is diffi-

cult because of chronic genitourinary symptoms and the high prevalence of bacteriuria in this population.¹⁵

Urinary Tract Infection: Risk Factors

Elderly patients, regardless of residential setting, are at a higher risk for developing a UTI than their younger counterparts. Factors that increase UTI risk in the elderly include widespread and frequent use of Foley catheters, decreased fluid intake, presence of urinary incontinence, and changes in personal hygiene related to a decline in functional status.^{1,8,12} Patients who are immobile, cognitively impaired, and/or immunocompromised, as well as those receiving antipyretics and/or analgesics, are also at increased risk.⁴ Other risk factors include prostatic hyperplasia and bacterial prostatitis in men, estrogen decline and a history of gynecologic surgery in post-

menopausal women, past history of UTIs, past/current antibiotic use, presence of urinary tract calculi, sexual activity, other forms of genitourinary instrumentation, and poor nutrition.^{1,8} For institutionalized patients, degenerative neurologic conditions such as Alzheimer's disease, Parkinson's disease, or cerebrovascular disease may be accompanied by a neurogenic bladder, which promotes UTIs through impaired voiding, increased residual volume, and urethral reflux.¹⁰

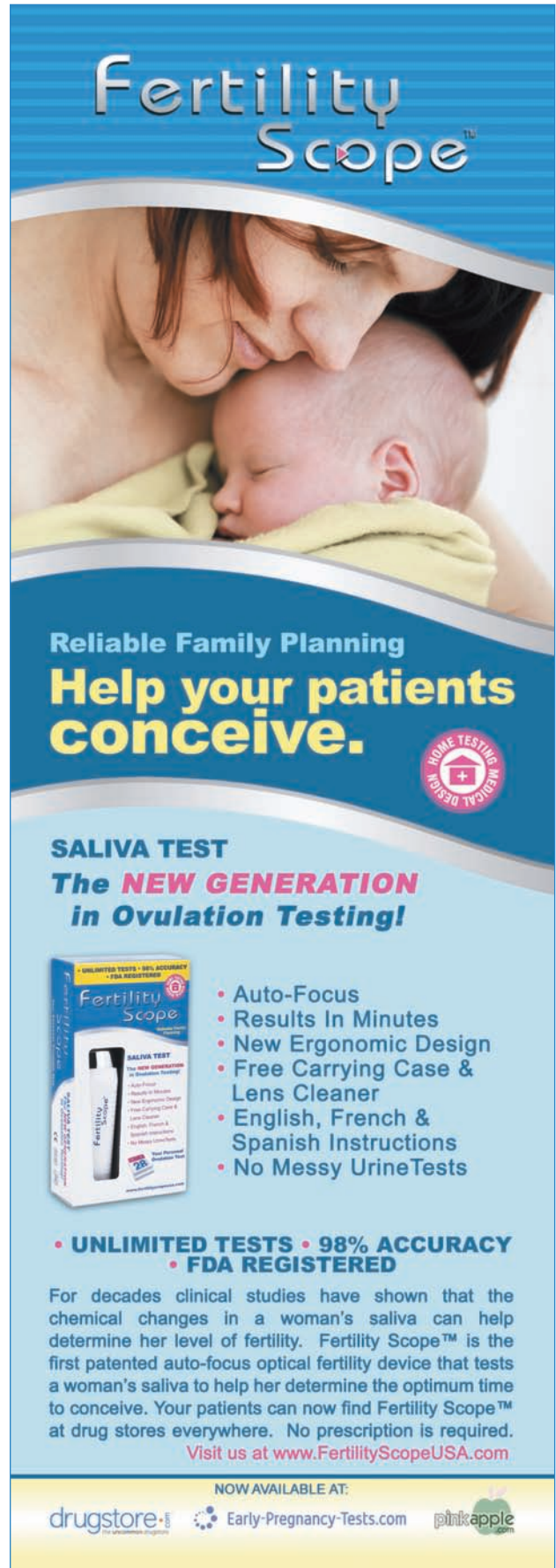
Ms Knight falls into the high-risk category for UTI because of her multiple risk factors, which include her immobility, her age, having a history of diabetes, being postmenopausal, and having a long-term in-dwelling Foley catheter.

Urinary Tract Infection: Signs/Symptoms and Diagnosis

Urine culture is useful only in *excluding* a UTI from the DDx but not in making the diagnosis of a UTI (bacteriuria is a common finding in the elderly population).^{7,9} Many practitioners diagnose a UTI in any LTCF resident who shows signs of clinical deterioration and a positive urine culture finding.⁹ This practice has contributed to overuse of antimicrobials and the increased rate of antimicrobial resistance.

Diagnosing true UTIs in the elderly is challenging but vital, because UTIs may cause substantial morbidity and mortality in this population. In the general population, a UTI is defined as the presence of a significant amount of a single pathogen ($>10^5$ CFU/mL and pus (>5 white blood cells [WBCs] per high-powered field) in the urine, accompanied by S/S.^{1,4,5,14} Classic S/S of a UTI are dysuria, urgency, frequent urination, flank pain, suprapubic pain, fever, cloudy urine, urine with foul odor, and recent-onset urinary incontinence.^{1,4,5} Of note, many of these S/S may be absent, masked, or difficult to assess in catheterized patients and in non-catheterized patients who are cognitively impaired.

Because so many elderly patients present with atypical S/S of a UTI, controversy exists regarding which ones are true manifestations.⁵ For example, elderly patients with a UTI may present with



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altered mental status, new-onset urinary incontinence, urinary retention, nausea/vomiting, confusion, agitation, lethargy, and/or increased falls—not necessarily S/S that one would associate with a UTI.¹ Other possible S/S of a UTI are hematuria, fever, cloudy or foul-smelling urine, chills, pain, tachycardia, tachypnea, hypotension, and abdominal tenderness.⁴

Urosepsis occurs when bacteria from the urinary tract enter the systemic circulation, causing a systemic inflammatory response. Presence of urosepsis is recognized as the first event in a cascade to multi-organ failure, which may be life threatening.¹⁶ Treatment of urosepsis entails prompt parenteral administration of antimicrobials. At first, a broad-spectrum antimicrobial such as a fluoroquinolone or a cephalosporin is used because of concern about resistant organisms. Once urine culture results become available, therapy can be switched to an agent with a narrower, more specific spectrum.⁹ Hospitalization is often required, during which intravenous (IV) hydration and IV antibiotics are given while the patient is closely monitored. Upon return to the LTCF, the resident's intake and output are closely monitored; cranberry tablets may be added to the daily medication regimen to decrease the risk of recurrent UTI.

Controversy persists regarding the use of cranberry juice or extract in treating UTIs. A systematic search of the Cochrane Database yielded no randomized controlled trials (RCTs) assessing the effectiveness of cranberry juice in this regard. Although no evidence supports the use of cranberry juice as a UTI treatment, some evidence supports its use as UTI *prophylaxis*. Cranberries contain a substance that can prevent bacteria from adhering to the bladder walls, perhaps preventing UTI development.^{8,12,17} Cranberry juice has also been shown to inhibit the growth of some bacteria by acidifying the urine.

Ms Knight is symptomatic and her urine culture is positive for the gram-negative bacterium Escherichia coli (>10⁶ CFUs/mL). Her serum WBC count was elevated at 13,000 cells/mcL. Chest radiographic findings are negative. These findings lead to a diagnosis of a UTI.

TABLE URINARY TRACT INFECTION TREATMENTS¹⁶

Diagnosis	Pathogen	Initial Empiric Antibiotic therapy	Therapy Duration
UTI with complicating factors	<i>Escherichia coli</i> , enterococci, <i>Klebsiella pneumoniae</i> , <i>Proteus mirabilis</i> , <i>Pseudomonas aeruginosa</i>	For gram-negative bacteria, use a fluoroquinolone; for enterococci, use ampicillin or amoxicillin, with or without gentamicin	10-14 days; elderly men should receive a 14-day course
Catheter-associated UTI	Depends on duration of catheterization	For gram-negative bacteria use fluoroquinolone; for gram-positive bacteria, use ampicillin or amoxicillin plus gentamicin	Remove catheter if possible, and treat 7-10 days; for patients with long-term catheters and symptoms, treat 5-7 days
Urosepsis	<i>Escherichia coli</i> , other Enterobacter spp	Cephalosporin or a third-generation fluoroquinolone	3-5 days after defervescence or control/elimination of complicating factor
UTI uncomplicated	<i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Proteus mirabilis</i> , <i>Staphylococcus aureus</i>	TMP-SMX, fluoroquinolone; Alternative: nitrofurantoin	3-7 days

UTI = urinary tract infection; TMP-SMX = trimethoprim-sulfamethoxazole.

Treatment

An exhaustive literature search suggests that no universal criteria or evidence-based guidelines for treating UTIs in the elderly exist.^{4,6} Further, no consensus on the definition and management of a UTI in the elderly population has been reached. More evidence-based studies are needed to help practitioners clarify this dilemma.¹⁸ Identifying clinically relevant symptoms in the geriatric population is challenging because of the atypical symptoms with which they can present. As a result, UTIs in the elderly pose more challenges in management than do those in the younger population. The Table lists accepted approaches for UTI treatment.¹⁶

Ms Knight's in-dwelling Foley catheter was promptly changed,

using strict aseptic technique, and antibiotic treatment with levofloxacin 500 mg IV x 7 days was initiated, as well as IV hydration with normal saline at 75 cc/hour. Vital signs and intake/outputs were monitored and documented during every shift.

Prevention

Although no specific guidelines to diagnose a UTI exist, various measures and interventions can be implemented to decrease the rate of UTIs in the elderly. The first step in UTI prevention is education, not only for healthcare practitioners, but also for patients and their families. Through education, NPs can better identify patients at highest risk for developing a UTI. NPs who

are familiar with S/S of a UTI may more likely to notice subtle changes in a patient and then order appropriate diagnostic tests and treatment. Through education, NPs can also educate patients and families, whether at home or in an LTCF, about measures they can implement to decrease UTI risk.

An indwelling urinary catheter is an accessible pathway for bacteria to enter the urinary tract. To reduce the rate of infection, proper hand washing before donning gloves for insertion and/or maintenance of the catheter is imperative.¹² Avoidance of catheter use and or removal of the catheter as soon as possible is another way to reduce infections in the elderly.^{10,12,19} Another intervention that substantially decreases infection risk is to maintain a closed drainage system.^{2,10,19} Aseptic technique at

catheter insertion and position of the drainage bag and tubing below the level of the bladder to prevent reflux are recommended. Limiting catheter trauma by securing the catheter appropriately and preventing obstruction of the catheter or drainage tubing, and assignment of catheterized patients to separate rooms when possible can also lessen the UTI rate.¹⁹ Studies comparing standard urinary catheters to antimicrobial or silver-impregnated catheters have demonstrated substantial reductions (30%-70%) in UTI rates.⁷

Dehydration in the elderly, a UTI risk factor, can be prevented by providing adequate fluid intake,²⁰ which increases urine output and flow and acts as a "washing" mechanism of the bladder. Dehydration may also decrease residual volume of urine, creating a breeding environment for bacteria that can develop into UTIs.²¹ Patients should be encouraged to drink several glasses of water a day to prevent dehydration.⁸ Offering water when older adults awaken in the morning, increasing the amount of water given with medications, having a variety of non-caffeinated beverages available throughout the day, and giving patients a daily fluid intake goal and encouraging them to record their daily intake are all ways to prevent dehydration and reduce the risk of developing a UTI.¹²

Patients should empty the bladder regularly and completely, possibly every 2 hours, and practice good bladder hygiene.⁸ Women should shower rather than bathe, wipe from front to back after a bowel movement, avoid products such as feminine sprays that may irritate the genital area, and remove bathing suits soon after swimming. Uncircumcised men

need to retract the foreskin when urinating. Both men and women should wear loose-fitting cotton undergarments and wash their genitals before and after sexual intercourse. Urinating after sexual intercourse also helps prevent contamination of the urinary tract.^{8,12}

For postmenopausal or frail elderly women with recurrent UTIs, NPs should assess for atrophic vaginitis or chronic bacteriuria. Atrophic vaginitis is relatively common and a significant risk factor for UTIs in older women. Topical (vaginal) estrogen has been shown to successfully treat atrophic vaginitis, reduce bacteriuria, and decrease the overall risk for UTIs in postmenopausal women.⁹ If atrophic vaginitis or bacteriuria is present, treatment with topical estrogen or an estradiol-containing vaginal ring should be considered to maintain the vaginal, urethral, and trigonal epithelium.⁷

Elderly patients who undergo invasive genitourinary procedures may be at a higher risk of sepsis secondary to damage and trauma to the mucosa. Infection may be prevented through use of antibiotic prophylaxis. Antibiotic therapy should be selected based on the pre-procedure infecting organism and should commence a short time before the procedure and continue briefly afterward. A single antibiotic dose 1 hour before the procedure may suffice.¹⁰

Ms Knight returned to her baseline level of health and function after 3 days of treatment. She is now alert and stable. UTI prophylaxis (daily cranberry tablets) has been initiated and she is being encouraged to increase her oral fluid intake,

which is reinforced by the nursing staff. Strict diabetic control continues, and a closed drainage system of her long-term Foley catheter is being maintained. The Foley catheter is also changed on a monthly basis to decrease UTI risk.

Conclusion

Evidence shows that elderly patients can present with an array of UTI S/S ranging from typical to atypical, many of which may not be verbalized or easily detected. NPs must be aware of subtle changes in elderly patients' behavior or appearance, as well as all potential S/S of a UTI so that diagnosis and treatment can be prompt in an effort to prevent life-threatening urosepsis. ■

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MEETINGS & EVENTS



OCTOBER 1-4, 2008: University of Washington School of Nursing Continuing Education (CNE) offers its Pacific NW 31st Annual Conference for Advanced Practice in Primary and Acute Care, which will take place at the Washington State Convention & Trade Center in Seattle. For more information, call CNE at (206) 543-1047, send an email to cne@u.washington.edu, or log on to [uwcne.org](http://www.uwcne.org)

OCTOBER 3-6, 2008: The Society of Urologic Nurses and Associates (SUNA) will hold its 39th Annual Conference at the Pennsylvania Convention Center and Philadelphia Marriott in Philadelphia, Pennsylvania. For more information, contact Linda Alexander at (856) 256-2300, ext. 2411, or linda@ajj.com. More news about SUNA can be found at www.suna.org

OCTOBER 13-16, 2008: The Diabetes Core Curriculum Workshop, a comprehensive diabetes update that is also helpful for the CDE exam, will take place at the Sheraton LaGuardia East Hotel in Queens, New York. For more information, contact Carol Molfetta by

phone at (631) 754-3663 or email at carol@healthbyte.org or log on to <http://www.healthbyte.org>

OCTOBER 15-18, 2008: The National Association of Nurse Practitioners in Women's Health will hold its 11th Annual Premier Women's Health Care Conference in Seattle, Washington. For more information, send an email to info@npwh.org or log on to the NPWH website at www.npwh.org

OCTOBER 17-19, 2008: Nurse Practitioners of Oregon (NPO) will hold its 2008 NPO Conference at the Hood River Best Western Inn. For more information, visit www.nursepractitionersoforegon.org

NOVEMBER 6-8, 2009: The Ohio Association of Advanced Practice Nurses (OAAPN) announces its 18th Annual Statewide Conference and Meeting, "APNs Providing Care Across the Lifespan." The event will take place at the Embassy Suites Hotel Columbus-Dublin, in Dublin, Ohio. Visit the OAAPN website at www.oaapn.org for more information.

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